IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)
a Massachusetts Corporation)
Plaintiff,)
v.) Civil No. 04-12457 PBS
Arthrex, Inc. a Delaware Corporation and)))
Pearsalls Ltd. a Private Limited Company of the United Kingdom)

Defendants.

DEPUY MITEK'S BRIEF IN REPLY TO DEFENDANTS' OPPOSITION TO DEPUY MITEK'S BRIEF IN SUPPORT OF ITS CLAIM CONSTRUCTION OF THE HUNTER PATENT— U.S. PATENT NO. 5,314,446

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T. Overview

Arthrex departs from the *Phillips* claim construction methodology in favor of improperly reading extraneous limitations and preferred embodiments into the claims to arrive at its resultoriented construction. Mitek, on the other hand, is doing exactly what the Phillips court directed - discerning the plain and ordinary meaning of the claim terms to one of ordinary skill in the art. Mitek's construction of "PE" and "consisting essentially of" is supported by the intrinsic and extrinsic record and should prevail.

II. Mitek's Construction of "Consisting Essentially of" Is Correct

A. **Arthrex Incorrectly Argues That The Reason "Consisting** Essentially Of" Was Added To The Claims Is Not Relevant

Arthrex wrongly asserts that the prosecution history and the reason why "consisting essentially of' was added to the claims are irrelevant to interpreting the meaning of that language. The prosecution history is intrinsic evidence that is *always* relevant to claim construction because it "demonstrat[es] how the inventor understood the invention and whether the inventor limited the invention in the course of the prosecution." Phillips v. AWH Corp., 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc). That the language being interpreted is "consisting" essentially of' does not change the analysis and somehow make the prosecution history irrelevant. Arthrex has cited no case to the contrary. And although Arthrex tries in vain to distinguish the cases Mitek cites, Arthrex fails.

Arthrex ignores that, in the cases Mitek cited, each term that is being construed was preceded by the language "consisting essentially of." In *Rheox*, it was "consisting essentially of calcium orthophosphate." Rheox, Inc. v. Entact, Inc., No. 98-3731 (MLC), 2000 U.S. Dist.

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LEXIS 21851, *2 (D. N. J. Aug. 21, 2000) (Ex.12)¹. In *Water Technologies*, it was "consisting essentially of triiodide." *Water Tech. Corp. v. Calco, Ltd.*, 850 F.2d 660, 666 (Fed. Cir. 1988). In *University of Florida*, it was "consisting essentially of . . . particle[s]... in the range of from about 355 to 710 [microns]." *University of Florida Res. Foundation, Inc. v. Orthovita, Inc.*, No. 1:96-cv-82-MMP, 1998 U.S. Dist. LEXIS 22648, *5 (N.D. Fla. Apr. 20, 1998) (Ex. 13). In each of these cases, the court looked to the prosecution history and the reasons why "consisting essentially of" was added to the claims. *See also Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 997-98 (Fed. Cir. 2006) (court considered why "comprising chromium catalyst" was amended to "consisting essentially of" chromium catalyst). Arthrex's attempts to suggest otherwise are based on a wishful reading of the cases.³

B. Arthrex Is Wrong in Asserting That Mitek's Construction Ignores The Specification

1. Mitek's Construction Of "Consisting Essentially" Is Grounded In The Specification

Arthrex mistakenly suggests that Mitek's construction ignores the patent specification. In both its opening brief and its response to Arthrex's brief, Mitek discussed the specification and

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¹ "Ex." refers to Mitek's claim construction exhibits. Exs. 1-13: Opening Brief, Exs. 14-18: Brief in Response to Arthrex's Claim Construction Brief, and Exs. 19-24: attached hereto.

Relying on the prosecution history to determine why "consisting essentially of" was added to a claim is unremarkable and reinforced by other nonprecedential Federal Circuit opinions. *See*, *e.g.*, *Pordy v. Land O'Lakes, Inc.*, No. 03-1182, 1202, 2004 U.S. App. LEXIS 8562, *16 (Fed. Cir. Apr. 30, 2004) (relied on prosecution history to determine whether titanium dioxide excluded from claim) (Ex. 19); *Laporte Pigments, Inc. v. Axel*, No. 01-1226, 2002 U.S. App. LEXIS 16593, *10 (Fed. Cir. Aug. 15, 2002) (examined prosecution history to determine what was excluded by amending claim to include "consisting essentially of") (Ex. 20); *Oscar Meyer Foods Corp. v. Conagra, Inc.*, No. 94-1247, -1248, 1994 U.S. App. LEXIS 36261 at *18-19 (Fed. Cir. Dec. 22, 1994) (same) (Ex. 21). Note, Arthrex miscites the *Oscar Meyer* case both as precedential and supporting its position (Arthrex CC Opp. Br. at 6).

³ Arthrex finally strains to distinguish *BASF* on the curious position that, because the language "consisting essentially of" was added during prosecution by an Examiner's amendment, the prosecution history is irrelevant. The salient point is that the prosecution history was considered.

focused on the specification's discussion of the mechanical blending of the two dissimilar materials (Mitek CC Br. at 8-12, Mitek CC Res. Br. at 1-2).⁴

2. Arthrex Mischaracterizes The Disclosure In The Specification

No amount of linguistic gymnastics can change Arthrex's attempt to read the preferred embodiment into the claims *via* the "consisting essentially of" language. Arthrex tries to justify this by arguing that, because the claim recites two of the materials that the specification refers to as preferred (PTFE and PET), it is not limiting the claims to a preferred embodiment when it imports the properties of the preferred embodiment into the claims (Arthrex CC Opp. Br. at 9). That a claim recites preferred materials, however, does not morph the claim into the preferred embodiment.

Along the way to justifying its strained construction, Arthrex mischaracterizes the specification as limiting the claimed first-fiber forming materials to weak and lubricious materials. But, as Mitek has already pointed out in its opening and responsive claim construction briefs (Mitek CC Br. at 17-18 and Mitek CC Res. Br. at 4-10), Arthrex's reading of the specification is wrong and is more-grounded in wishful thinking than in the clear words of the specification.

C. Arthrex Incorrectly Characterizes Mitek's Construction

Arthrex is off the mark in suggesting that Mitek is somehow trying to expand the scope of Claim 1 with its "consisting essentially of" construction. Arthrex is reading too much into Mitek not mentioning the word "suture." There was no reason for Mitek to recite the word "suture" since it is explicitly recited in the claim. Mitek is not trying to recapture its broader original "braid" claim with its construction of the basic and novel characteristics of the

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⁴ "Mitek CC Br." means "Mitek's Brief in Support of its Claim Construction" and "Mitek CC Res. Br" means "Mitek's Brief in Response to Arthrex's Claim Construction Brief. "Arthrex CC Opp. Br." means Arthrex's Opposition to Mitek's Brief in Support of its Claim Construction.

invention, as Arthrex incorrectly argues. Also, the original claim included bioabsorbable materials, while Claim 1 does not.

D. Mitek Did Not Mischaracterize Arthrex's Construction

Arthrex falsely accuses Mitek of misstating Arthrex's construction of "consisting essentially of." But Mitek did no such thing. Throughout discovery, Arthrex's position was that the language "consisting essentially of" excluded coatings from the claims. Mitek took that to mean that Arthrex's construction of "consisting essentially of" excluded coatings, as its summary judgment briefing further indicates (See, e.g., Ex. 6 at 8-9; Ex. 22 at 217:8-219:17). In that briefing, Arthrex argues that coatings necessarily affect handleability and therefore coated sutures are excluded from the claims (Arthrex SJ Br. at 13-16).⁵ But perhaps now recognizing that it would be unsuccessful in sneaking a no-coating limitation into the claim through the "consisting essentially of" language, Arthrex has backed away from that earlier construction. But either way, there should be no mistake, Mitek did not expressly and unequivocally disclaim coated sutures from the scope of its claims (Mitek CC Br. at 10-14).

Mitek's Construction of "PE" Is Correct III.

Mitek's Construction Of "PE" is Consistent with the Directives of A. **Phillips**

Arthrex falsely accuses Mitek of having jettisoned the *Phillips* claim construction model in favor of the *Texas Digital* model.⁶ But Mitek did no such thing. Mitek is doing exactly what

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⁵ "Arthrex SJ Br." means Defendants' Brief in Support of their Motion for Summary Judgment. ⁶ Arthrex's position that Mitek is applying the *Texas Digital* approach to claim construction is unsupported. Texas Digital Sys. v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002). Texas Digital was different than the claims here. The terms disputed in Texas Digital were not terms of art, like PE. The non-section-112-paragraph-six claims being construed in Texas Digital involved terms with ordinary meaning: "repeatedly substantially simultaneously activating" (id. at 1205); "selectively controlling the durations of time intervals of activation" (id. at 1206-07); "display areas" (id. at 1209-10); "background areas" (id.); and "display areas arranged in a pattern." (id. at 1210-11).

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the *Phillips* court directed -- discerning the plain meaning of the claim term "PE" to one of ordinary skill in the art.

In interpreting "PE," Mitek properly started with the plain meaning of the claim term and then turned to the specification. Because PE is a technical term, Mitek properly turned to extrinsic evidence to determine its meaning to persons skilled in the art. Arthrex cannot and does not dispute that "PE" is a term of art. *Phillips* endorsed using extrinsic evidence in these kinds of situations. *Phillips*, 415 F.3d at 1314 (extrinsic evidence concerning meaning of technical terms should be considered where meaning of claim term as understood by persons of skill in art is not immediately apparent from intrinsic record). Thus, Mitek properly relied on Dr. Hermes' testimony, chemical dictionaries, and chemical encyclopedias as tools to determine the meaning of "PE."

By contrast, Arthrex does not have a shred of evidence to support its strained and vague construction that "PE" means general purpose PE. Arthrex's only "evidence" is attorney argument and an inadmissible third party commercial brochure for a particular kind of commercial ultra high molecular weight PE. But none of that is evidence that is relevant to the construction of "PE." Mitek's construction of "PE" is well-supported and should prevail.

B. Mitek's Extrinsic Evidence Is Probative On the Meaning of "PE"

Arthrex tries to impeach Mitek's extrinsic evidence, but its tactics fail. Arthrex puts words in Dr. Hermes' mouth when it refers to so-called "serious deficiencies" in the encyclopedia reference on which he relied (Arthrex CC Opp. Br. at 12). Notably, Arthrex selectively excerpted his testimony. When Dr. Hermes' testimony on that point is read in context, it is clear that he was not admitting that the source had serious deficiencies, but that the reference was probative of the meaning of "PE" at the time of the claimed invention (Ex. 23 at 246:3-248:14).

Arthrex again selectively excerpts Dr. Hermes' testimony to suggest that he "mischaracterized" a reference in his report (Arthrex CC Opp. Br. at 12). But Dr. Hermes did not mischaracterize anything. After a full read of his answer, it is clear that Dr. Hermes was referring to a confusion between exhibits, not a mischaracterization of a reference. Notably, Arthrex cuts off his testimony at line 14 when his entire response goes to line 16:

- 13 A. I believe I mischaracterized the
- 14 reference in the report. I don't -- I may find it
- 15 in reference 19, but I believe that I'm referring to
- 16 reference 18." (Ex. 23 at 244:13-16).

When the evidence is considered in its full, fair, and complete context, the evidence supports

Mitek's construction. Because Arthrex has no evidence of its own, but only attorney argument,

Mitek's construction of "PE" is the one that should prevail.

C. Mitek's 446 Patent Specification Is Consistent With Ultra-High Molecular Weight PE

Arthrex wrongly asserts that ultra-high molecular weight PE is the opposite of what is disclosed in the specification for the first set of fiber forming materials, and therefore, *Phillips* supports its position. Although Mitek addressed these issues extensively in the context of its opposition to Arthrex's motion for summary judgment and refers to the Court to that discussion (Mitek SJ Opp. Br. at 5-10)⁷, it highlights certain points here.

- Arthrex wrongly contends that the first fiber-forming materials are described as weak, and that ultra-high molecular weight PE is not weak. Arthrex refers to a sentence that describes certain "braids," but that sentence does not say that all braids or materials, much less all first fiber forming materials, are weak. Nevertheless, ultra-high molecular weight PE is weak in compression and knot holding strength (Mitek SJ Opp. Br. at 11 & 12, fn 9).
- Arthrex wrongly asserts that the first fiber-forming materials are described as being only for pliability, and that ultra-high molecular weight PE does not provide pliability (Arthrex SJ Br. at 11). But the specification has broader teachings and

 $^{^7}$ "Mitek SJ Opp. Br." means Mitek's Memorandum in Opposition to Arthrex's Motion for Summary Judgment.

- discusses embodiments in which the first fiber-forming materials are for "compliance, or surface lubricity," not just pliability (Mitek SJ Opp. Br. at10).
- Contrary to Arthrex's assertions, lubricating yarns such as ultra-high molecular weight PE can provide pliability because of the increased fiber-to-fiber mobility (Mitek SJ Opp. Br. at13).
- Arthrex concocts a weak/strong theme that ignores the specification's broader teachings and relies only on a "most preferred embodiment" of PTFE and PET (Arthrex SJ Br. at 11).

Other parts of the specification reinforce that ultra-high molecular weight PE is within the claimed "PE." The specification states that the first set of yarns "can be any materials capable of being spun into continuous filaments, [and are a]dvantageously... nonmetallic" (Ex. 1 at 3:52-56). Ultra-high molecular weight PE is such a material (Ex. 16 at ¶17). The specification explains that in a "preferred embodiment, the first set of yarns act as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid" (Ex. 1 at 4:11-14). PE, including ultra-high molecular weight PE is a lubricious material (Ex. 9 at 52:24-53:1; Ex. 8 at 239:10-13). The specification explains that the first set of yarns may be "non-absorbable polymers" (Ex. 16 at ¶17; Ex. 1 at 4:10-11). Ultra-high molecular weight PE is a non-absorbable polymer. The specification describes the first set of yarns as being made from fiber-forming materials (Ex. 16 at ¶17; Ex. 1 at 2:45-46). Ultra-high molecular weight PE is a fiber-forming material. Therefore, the description of the first-fiber forming materials is consistent with ultra-high molecular weight PE and not the opposite as Arthrex urges this Court to believe. Arthrex's attempts to buttress its misguided position with reference to Burgess fall short for reasons stated in Mitek's Opening and Responsive Claim Construction Briefs (Mitek CC Br. at 19-21; Mitek CC Res. Br. at 10-12)8.

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⁸ Arthrex incorrectly asserts that Burgess discloses a certain braided combination of ultra-high molecular weight PE and PET (Arthrex Opp. Br. at 17-18). Arthrex's statements are unsupported attorney argument. Mitek disputes Arthrex's assertions (Ex. 24 at ¶¶88-93, 104-106, 111-113, 117).

Date: September 15, 2006 DEPUY MITEK, INC., By its attorneys,

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CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that a true and correct copy of:

DEPUY MITEK'S BRIEF IN REPLY TO ARTHREX'S BRIEF IN RESPONSE TO MITEK'S CLAIM CONSTRUCTION BRIEF RE: MITEK'S HUNTER **PATENT— U.S. PATENT NO. 5,314,446**

was served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

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Dated: September 15, 2006 /s/ Erich M. Falke_____ Erich M. Falke

EXHIBIT 19

LEXSEE 2004 US APP LEXIS 8562

WILLIAM T. PORDY and CARBERRY CORPORATION, Plaintiffs-Appellants, v. LAND O'LAKES, INC., Defendant-Cross Appellant.

03-1182, 03-1202

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

97 Fed. Appx. 921; 2004 U.S. App. LEXIS 8562

April 30, 2004, Decided

NOTICE: [**1] THIS DECISION WAS ISSUED AS UNPUBLISHED OR NONPRECEDENTIAL AND MAY NOT BE CITED AS PRECEDENT. PLEASE REFER TO THE RULES OF THE FEDERAL CIRCUIT COURT OF APPEALS FOR RULES GOVERNING UNPUBLISHED CITATION TO OR NONPRECEDENTIAL OPINIONS OR ORDERS.

SUBSEQUENT HISTORY: Rehearing denied by Pordy v. Land O'Lakes, Inc., 120 Fed. Appx. 313, 2004 U.S. App. LEXIS 27915 (2004)

Summary judgment denied by Pordy v. Land O'Lakes, Inc., 2005 U.S. Dist. LEXIS 16281 (S.D.N.Y., Aug. 8, 2005)

PRIOR HISTORY: Pordy v. Land O'Lakes, Inc., 2002 U.S. Dist. LEXIS 22296 (S.D.N.Y., Nov. 15, 2002)

DISPOSITION: Affirmed in part, vacated in part, reversed in part, and remanded in part for new trial on issue of anticipation.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiffs inventor and patent holder alleged defendant competitor infringed a coffee creamer patent. The United States District Court for the Southern District of New York granted the competitor's motion for judgment as a matter of law (JMOL), reversing a jury's verdict of infringement. Plaintiffs appealed. The competitor cross-appealed, alleging errors in claim construction, jury instructions on effective filing date, and an evidentiary ruling.

OVERVIEW: The transitional phrase "consisting essentially of" was correctly interpreted as meaning the invention was open to unlisted ingredients that did not materially affect basic and novel properties, which were correctly identified as taste, body, appearance, mouthfeel,

and whitening ability. Because the competitor did not object to plaintiffs' tests tending to show titanium dioxide did not alter whitening ability, the tests were admitted and could provide substantial evidence to support the jury's finding. During patent prosecution, the inventor's statement differentiating prior art highlighted that titanium dioxide would not affect his product; it was not a surrender of a formulation that simply added titanium dioxide to his formula. But, because the original application did not provide sufficient disclosure for the claims in the continuation-in-part application, on higher percentages of butterfat or a substitute, it was error to deny JMOL to the competitor on that issue. The original application's filing date did not apply. Thus, the issue on whether products produced after the original filing date and before the continuation filing date would make the patent anticipated remained.

OUTCOME: The appellate court vacated the grant of JMOL to the competitor, but affirmed as to the issue of claim construction. It reversed the district court on the issue of effective filing date and thus vacated the jury's verdict and remanded the case to the district court for trial on the issue of whether prior art anticipated the patent. The district court was to reinstate the jury's verdict if the competitor did not prove anticipation.

LexisNexis(R) Headnotes

Civil Procedure > Trials > Judgment as Matter of Law > General Overview

Civil Procedure > Appeals > Standards of Review > De Novo Review

Civil Procedure > Appeals > Standards of Review > Substantial Evidence > General Overview

[HN1] A court of appeals reviews a district court's grant or denial of judgment as a matter of law (JMOL) de novo by reapplying the JMOL standard. Factual findings made

by the jury in arriving at its verdict are to be upheld unless the party moving for JMOL shows that when the correct legal standard is applied there is not substantial evidence to support a finding in favor of the nonmovant.

Civil Procedure > Appeals > Standards of Review > De Novo Review

Patent Law > Infringement Actions > Claim Interpretation > General Overview

Patent Law > Jurisdiction & Review > Standards of Review > General Overview

[HN2] Claim construction is a matter of law that a court of appeals reviews de novo.

Civil Procedure > Trials > Judgment as Matter of Law > General Overview

[HN3] To prevail on a motion for judgment as a matter of law following a jury trial, the moving party must show that the jury's findings, presumed or express, are not supported by substantial evidence.

Civil Procedure > Appeals > Standards of Review > Substantial Evidence > General Overview

[HN4] In determining whether the jury's verdict is supported by substantial evidence, the court must draw all reasonable inferences in favor of the prevailing party, and not make credibility determinations or substitute the court's view of the conflicting evidence for that of the jury. Substantial evidence means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.

Civil Procedure > Trials > Jury Trials > Province of Court & Jury

[HN5] It is not for the court to determine the credibility and veracity of the witnesses and their studies, as these questions are properly reserved for the jury.

Civil Procedure > Trials > Jury Trials > Province of Court & Jury

Patent Law > Infringement Actions > Infringing Acts > General Overview

[HN6] After the court has defined a patent claim, the task of determining whether the construed claim reads on the accused product is for the finder of fact.

Patent Law > Claims & Specifications > Claim Language > General Overview

Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN7] The limiting term "consists essentially of" in a patent claim represents a middle ground between the open-ended term "comprising" and the closed-ended phrase "consisting of." In view of the ambiguous nature of the phrase, it has long been understood to permit inclusion of components not listed in the claim, provided that they do not materially affect the basic and novel properties of the invention.

Patent Law > Claims & Specifications > Claim Language > General Overview

Patent Law > Infringement Actions > Prosecution History Estoppel > General Overview

[HN8] Statements made during prosecution history may limit the scope of the patent. However, the clear language of the claims will be limited to exclude an interpretation only where the accused infringer can demonstrate that the patentee surrendered that interpretation with reasonable clarity and deliberateness.

Patent Law > Infringement Actions > Claim Interpretation > General Overview

Patent Law > Infringement Actions > Prosecution History Estoppel > General Overview

[HN9] An interpretation of an unambiguous claim is limited by prosecution history only to the extent that the patentee clearly and deliberately surrendered that interpretation.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview

Patent Law > U.S. Patent & Trademark Office Proceedings > Continuation Applications > Copendency & Disclosure

Patent Law > U.S. Patent & Trademark Office Proceedings > Continuation Applications > Priority

[HN10] When one files a continuation-in-part application, matter disclosed in the parent application is entitled to the benefit of the filing date of the parent application. Determination of whether a priority document contains sufficient disclosure under the first paragraph of 35 U.S.C.S. § 112 is a question of law. To decide whether a continuation-in-part application receives the benefit of an earlier filing date, a court must examine whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.

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Patent Law > Anticipation & Novelty > Fact & Law Issues

[HN11] Anticipation, in the context of patent infringement, is a question of fact.

Civil Procedure > Trials > Jury Trials > Province of Court & Jury

Civil Procedure > Appeals > Remands

[HN12] A question of fact is initially best resolved by the district court.

Patent Law > Anticipation & Novelty > General Overview

Patent Law > Infringement Actions > Burdens of Proof [HN13] A defendant in a patent infringement case must prove anticipation by clear and convincing evidence.

Patent Law > Infringement Actions > Defenses > Patent Invalidity > General Overview

[HN14] A party seeking to establish that particular claims are invalid must overcome the presumption of validity in 35 U.S.C.S. § 282 by clear and convincing evidence.

Civil Procedure > Trials > Judgment as Matter of Law > General Overview

[HN15] The trial judge continues to be bound by a jury's finding even if its verdict is vacated, so long as the underlying factfinding is not impugned.

JUDGES: Before SCHALL, GAJARSA, and PROST, Circuit Judges.

OPINION: [*923] PER CURIAM

William T. Pordy, M.D., and Carberry Corporation (collectively, "Pordy") brought a patent infringement action against Land O'Lakes, Inc. ("Land O'Lakes") in the United States District Court for the Southern District of New York. Following a trial, the jury found Pordy's patent to be infringed and granted damages against Land O'Lakes. The district court granted the defendant's motion for judgment as a matter of law ("JMOL") and reversed the jury's verdict of patent infringement. Pordy appeals this decision. Land O'Lakes cross-appeals, alleging errors in the district court's (1) claim construction; (2) jury instructions on effective filing date; and (3) evidentiary ruling. Because we find that the jury had before it evidence sufficient to support its findings of infringement and willful infringement, we vacate the court's grant of JMOL. We affirm the district court [**2] on the issue of claim construction. Finally, we reverse the district court on the issue of effective filing date. Accordingly, we vacate the jury's verdict, and remand the case to the district court for trial on the issue of whether, in light of the later filing date, the prior art anticipates the patent-in-suit.

I. BACKGROUND

A. The '670 Patent

Dr. William Pordy is the named inventor on the U.S. Patent No. 5,480,670 (the "'670 patent"), which is directed to a low-fat, low-cholesterol, low-calorie coffee creamer composition of all-natural ingredients meant to imitate Half & Half creamers. n1 The patent is assigned to Carberry Corp, a Pordy-owned company. The patent contains nineteen claims. The only claims at issue in this suit are Claims 1 and 19 of the '670 patent. Claims 1 and 19 read as follows:

- 1. A liquid coffee lightener which consists essentially of milk having approximately 8.5% milk solids by weight and 1-3.57% [*924] butterfat by weight; 2-12% by weight of additional milk solids added to said skim milk; and a natural fat substitute 03.3 [sic]-10% by weight, said coffee lightener having total solids content within the range of 11-28% by [**3] weight and a total fat and fat mimetic content to simulate the taste, body, appearance, mouthfeel and organoleptic properties of Half & Half while being substantially lower in fat, saturated fat, and calorie content of and not exceeding the cholesterol content of conventional creamers.
- 19. A fat free liquid coffee lightener which consists essentially of milk having approximately 8.5% milk solids by weight and "B" grams of butterfat by weight; 2-12% by weight of additional milk solids added to said milk; and an all natural fat substitute 0.3-10% by weight, said coffee lightener having, in a substantially standard 0.5 oz. Serving "V" of approximately 15 mL, total solids content within the range of 11-28% weight and total fat and mimetic content to simulate the taste, body, appearance, mouthfeel and organoleptic properties of Half & Half while being substantially lower in total fat, saturated fat, and calorie content of and not exceeding the cholesterol content of conventional creamers, and wherein the

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butterfat content "B and the volume of the serving "V" are related as follows:

 $V \times B = 50$

Where V is in mL and B is in grams.

U.S. Patent No. 5,480,670, cl. 9, 11. [**4] 39-49; cl. 10, ll. 37-54.

n1 The '670 Patent is a continuation-in-part of Application No. 07/890,803, (the "803 application") filed June 1, 1992. The '803 application resulted in U.S. Patent No. 5,366,751 (the "751 patent"), as well as the '670 patent.

Before the '670 patent issued, Pordy met with executives at Land O'Lakes' headquarters to discuss his confidential business plan to market his invention. At that meeting, he disclosed the nature and the benefits of his invention. According to Pordy's testimony, Land O'Lakes' executives expressed interest; however, no agreement was reached to purchase either Pordy's business plan or a right to use his invention. Subsequent to the meeting, but before the issuance of the '670 patent, Land O'Lakes entered the creamer market with a new product called "Gourmet Fat Free Half & Half." The only difference between Pordy's invention and Land O'Lakes' product is the inclusion of titanium dioxide (0.4% by weight) in the latter.

After the issuance of the '670 patent, Pordy [**5] filed suit against Land O'Lakes for breach of contract, trade secret appropriation, common law misappropriation, and patent infringement. n2

n2 The trial court also granted summary judgment in Land O'Lakes' favor as to all of Pordy's state law claims in view of the statute of limitations. Pordy only appeals the trial court's JMOL reversing the jury's infringement findings on the '670 patent.

B. Proceedings Below

The district court held a Markman hearing to construe the claims of the '670 patent. Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). The court interpreted the transitional phrase "consisting essentially of" as follows:

The phrase "consists essentially of" means that the invention is "open to unlisted ingredients that do not materially affect the basic and novel properties [*925] of the invention." PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998). [**6] The "basic and novel properties" of the invention at issue are its "taste, body, appearance and mouthfeel," Patent '751 at col. 8, ln. 68, in addition to its "whitening ability."

The district court also refused to specifically exclude whiteners containing sugar from the scope of the patent.

n3 The court stated that it "declines to rule . . . as to what substances in what quantities may or may not materially affect [the] basic and novel properties of the invention." Thus, according to the district court, a coffee whitener containing sugar is beyond the scope of the patent only if the presence of sugar materially affects "taste, body, appearance and mouthfeel" of the product.

The question presented by the district court's construction, therefore, was whether the inclusion of titanium dioxide "materially affects the basic and novel properties of the invention." *PPG Indus.*, 156 F.3d at 1354.

At trial, Pordy submitted the results of an experiment that he conducted comparing his product [**7] to that of Land O'Lakes'. The experiment was not carried out in a rigorously-controlled scientific environment. The subjects chosen for these experimental trials were those individuals who happened to walk by the back entrance of Pordy's building on a particular morning. One of the subjects was Pordy's patent attorney.

Pordy prepared two samples containing the ingredients specified in Land O'Lakes' formula for Gourmet Fat Free Half & Half, other than the stabilizers and emulsifiers. Sample One contained 0.4% titanium dioxide, while Sample Two did not. In a double blind study, eleven subjects were asked to comment on the color differences between the two samples as they appeared in coffee. Nine of the eleven subjects could not distinguish between the two samples.

Four other subjects were asked to compare the two samples directly (i.e., not in coffee). Three of the four subjects stated that the samples were the same color. The 97 Fed. Appx. 921, *; 2004 U.S. App. LEXIS 8562, **

fourth stated that Sample One (containing titanium dioxide) was slightly lighter than Sample Two. Based on these experiments, Pordy stated at trial that "it was very clear, abundantly clear that [the titanium dioxide] was not material, that it did not affect [**8] the composition."

Land O'Lakes argued at trial that the inclusion of the titanium dioxide in its product did indeed materially affect the product's whitening ability. Land O'Lakes' witnesses testified that titanium dioxide is added to coffee whiteners to make the product appear whiter and to increase whitening ability. An executive from Land O'Lakes testified that he used a colorimeter to compare the marketplace sample of Gourmet Fat Free Half & Half to Pordy's bench-top samples with and without titanium dioxide. He further testified that the bench-top sample with titanium dioxide "had the typical color of Fat Free Half & Half" while the bench-top sample without titanium dioxide was "significantly lower in whiteness." He concluded that "titanium dioxide is probably about 80 percent of the appeal of this product to the consumers. That's how important it is."

At the end of submitted evidence, Land O'Lakes moved for summary judgment of non-infringement. The court denied Land O'Lakes' motion by stating:

Well, while again I reiterate for the hundredth time how close I think this particular issue is and I note that only for purposes of the record on appeal, I think when all is said [**9] and done that there is enough evidence here, and it is barely enough, but there is enough here from which a reasonable juror could conclude that titanium dioxide was not necessarily material to the color of Land O'Lakes' formula or its mixture, its product.

I cannot conceal how unlikely that seems to me based on all the evidence taking it, if I were to take this, as the finder of fact, but I'm not the finder of fact, and for purposes of this motion, I have to consider the evidence most favorably to the plaintiffs....

And I'm convinced that while this was a fair test and his opinions were received as an expert, so, in the totality of the situation, I will deny the motion.

The jury found that Land O'Lakes' Gourmet Fat Free Half & Half infringed claims 1 and 19 of Pordy's '670 patent. The jury awarded Pordy compensatory damages of \$ 2,578,431 and willfulness damages of \$ 421,569, for a total award of \$ 3 [*926] million. Land O'Lakes re-

newed its motion for judgment as a matter of law and filed a memorandum in support thereof. Land O'Lakes argued that the evidentiary basis was insufficient to sustain the jury's verdict because, inter alia, Pordy's evidence failed to show that [**10] titanium dioxide does not materially affect the composition of the whitener.

Eleven months after the jury reached its decision, the district court vacated the jury's verdict and entered judgment for Land O'Lakes. In so doing, the district court stated:

No juror could have reasonably relied upon [the results of Pordy's experiment], given, e.g., that Dr. Pordy had "homebaked" the two key samples, that he gave the test to only eleven subjects (a statistically insignificant number), that he kept no record of the questions put to these subjects (or of whether they were consistent as between subjects), and that, most remarkably, the subjects, consisting of persons who "walked past his back door," included various persons plainly biased in his favor, such as his own patent lawyer.

Pordy timely filed a Notice of Appeal. Land O'Lakes timely served its Notice of Cross-Appeal contesting the district court's claim construction, jury instructions, as well as its evidentiary rulings. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

A. Standard of Review

[HN1] We review a district court's grant or denial of JMOL de novo by [**11] reapplying the JMOL standard. Ericsson, Inc. v. Harris Corp., 352 F.3d 1369, 1373 (Fed. Cir. 2003). "Factual findings made by the jury in arriving at its verdict are to be upheld unless the party moving for JMOL shows that (when the correct legal standard is applied) there is not substantial evidence to support a finding in favor of the nonmovant." Markman, 52 F.3d at 975. [HN2] Claim construction is a matter of law that we review de novo. Markman, 52 F.3d at 970-71.

B. Judgment as a Matter of Law

Pordy appeals the grant of JMOL in favor of Land O'Lakes, and argues that there was substantial evidence to support the jury's verdict.

[HN3] To prevail on a motion for JMOL following a jury trial, the moving party "must show that the jury's findings, presumed or express, are not supported by sub-

stantial evidence." Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998) (internal citations and quotations omitted). The burden therefore was on Land O'Lakes to show that Pordy's experiments did not constitute "substantial evidence."

We have noted that [HN4] "in determining whether the jury's verdict is supported by substantial [**12] evidence, 'we must draw all reasonable inferences in favor of the prevailing party, and not make credibility determinations or substitute our view of the conflicting evidence for that of the jury." Eaton Corp. v. Rockwell Int'l Corp., 323 F.3d 1332, 1345 (Fed. Cir. 2003) (quoting SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp., 225 F.3d 1349, 1355 (Fed. Cir. 2000)). "Substantial evidence . . . means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Consol. Edison Co. v. NLRB, 305 U.S. 197, 229, 83 L. Ed. 126, 59 S. Ct. 206 (1938).

At trial, both parties submitted evidence of tests conducted on their products. Pordy's tests tended to show that titanium dioxide does not alter the whitening ability of his invention, while Land O'Lake's tests tended to show that it does. To be sure, [*927] Land O'Lakes' studies were more sophisticated than Pordy's. While Land O'Lakes used colorimeters, Pordy produced testing samples at home, and tested them on a very small number of subjects, some of whom may have been biased in Pordy's favor. At trial, however, Land O'Lakes did not object to Dr. Pordy's methods, or to his qualifications as an expert witness [**13] in the field of coffee whiteners. Having failed to preserve this argument by objecting, Land O'Lakes cannot subsequently attack the court's decision to admit the studies. With Pordy's studies admitted, the only question remaining was their credibility. Land O'Lakes had sufficient opportunity to crossexamine Pordy and to point out the weaknesses in his studies to the jury. The jury in turn was free to credit or not to credit Pordy's veracity and ability to conduct a proper scientific experiment. It chose to believe Pordy. [HN5] It is not for the court to determine the credibility and veracity of the witnesses and their studies, as these questions are properly reserved for the jury. Akamai Techs., Inc. v. Cable & Wireless Internet Servs., Inc., 344 F.3d 1186, 1192 (Fed. Cir. 2003).

The conflicts between Pordy's evidence and Land O'Lakes' evidence was a question of fact for the jury to resolve. See *PPG Indus.*, 156 F.3d at 1355 [HN6] ("After the court has defined the claim . . . the task of determining whether the construed claim reads on the accused product is for the finder of fact.") We agree with the district court's original conclusion that the issue is a [**14] close one. However, because we must draw all reasonable inferences in favor of Pordy, SIBIA, 225 F.3d at

1355, we believe that there was substantial evidence to support the jury's finding.

Accordingly, we vacate the JMOL entered by the district court. For the reasons set forth below, see Part III.D, post, we also vacate the jury's verdict.

C. Claim Construction

Land O'Lakes cross-appeals on the issue of claim construction, arguing that the court below erred in not specifically excluding products containing titanium dioxide and/or sugars. We disagree.

It is well settled that [HN7] the limiting term "consists essentially of . . . represents a middle ground between the open-ended term 'comprising' and the closed-ended phrase 'consisting of." AK Steel Corp. v. Sollac and Ugine, 344 F.3d 1234, 1239 (Fed. Cir. 2003). "In view of the ambiguous nature of the phrase, it has long been understood to [**15] permit inclusion of components not listed in the claim, provided that they do not 'materially affect the basic and novel properties of the invention." Id. (quoting PPG Indus., 156 F.3d at 1354 (Fed. Cir. 1998)); see also In re Janakirama-Rao, 50 C.C.P.A. 1312, 317 F.2d 951, 954 (C.C.P.A. 1963).

The '670 patent was drawn to a substance meant to whiten coffee and to "simulate the taste, body, appearance, mouthfeel and organoleptic properties of Half & Half while being substantially lower in fat, saturated fat, and calorie content of and not exceeding the cholesterol content of conventional creamers." '670 patent, col. 9, ll. 39-50; col. 10, ll. 36-53. The relevant "basic and novel properties of [Pordy's] invention," AK Steel Corp., 344 F.3d at 1239, are specified in the claims and include: (1) whitening ability, (2) taste, (3) body, (4) appearance, (5) mouthfeel, (6) organoleptic properties, and (7) fat and cholesterol content. The district court, relying on our precedent, correctly identified these properties, and construed the claim accordingly.

Land O'Lakes argues that during the prosecution of the '670 patent, Pordy surrendered coffee whiteners that include [*928] titanium dioxide. Land O'Lakes draws that inference from the statement Pordy made during the prosecution comparing his invention to the prior art: "additionally, and most important, Baker et. al. [prior art] [**16] requires the addition of a whitening agent (artificial color-titanium dioxide) to produce a product which [sic] has an acceptable appearance."

[HN8] Statements made during prosecution history may limit the scope of the patent. See Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.") However, the clear

language of the claims will be limited to exclude an interpretation "only where the accused infringer can demonstrate that the patentee surrendered that interpretation with reasonable clarity and deliberateness." Schumer v. Lab. Computer Sys., Inc., 308 F.3d 1304, 1313 (Fed. Cir. 2002) (emphasis added; internal citations and quotations omitted).

Land O'Lakes misreads the purpose and the effect of Pordy's statement on titanium dioxide. Pordy's statement differentiating his invention from the prior art highlighted that his formula is sufficiently white without titanium dioxide, and that the addition of titanium dioxide would not affect his product. Pordy's statement thus cannot be [**17] read as a clear and deliberate surrender of a formulation that simply added titanium dioxide to his formula, precisely because he claims that the addition of titanium dioxide to his product would not alter it in any appreciable way. The district court was correct in refusing to exclude products that contain titanium dioxide from the scope of the '670 patent, provided that the addition of this material did not change the whitening ability of the product.

Next, Land O'Lakes argues that the district court erred when it refused to exclude products containing sugar from the scope of the '670 patent. Land O'Lakes makes its argument by quoting the following language from the prosecution history:

Finally Bookwalter et al. [prior art] teaches a milk concentrate produced without an emulsifier but with 3-40% by weight of edible oil and 0-35% by weight of sugar. Additionally, both of these latter ingredients, particularly the ranges noted, are inconsistent with the present invention because the product defined in the claims does not use sugar nor an edible oil of the type taught in the reference.

(emphasis added).

Land O'Lakes argues that this language excludes [**18] all sugars other than lactose (a sugar naturally occurring in milk).

Once again, Land O'Lakes fails to understand our precedent. As explained above, [HN9] an interpretation of an unambiguous claim is limited by prosecution history only to the extent that the patentee clearly and deliberately surrendered that interpretation. Id.

Land O'Lakes' argument gives short shrift to the words that qualify Pordy's statement, "of the type taught

in the reference." The reference teaches only sucrose and dextrose. Thus, at most, only products containing those two specified sugars are excluded from the scope of the '670 patent. Furthermore, the Bookwalter reference does not teach a coffee lightener, but rather a milk concentrate product. Given these two facts, we cannot conclude that Pordy clearly and deliberately surrendered an interpretation that would include sugars in the scope of the patent. Id.

Additionally, Land O'Lakes' argument suffers from a more fundamental problem. [*929] Land O'Lakes would have us equate "sugar" with any substance that happens to contain sugar, such as corn syrup. n4 Taking this argument to its logical conclusion, Pordy's milk whitener could not contain any milk because [**19] milk contains lactose, which is itself a sugar. Land O'Lakes understands that such an argument would be absurd, so it concedes that lactose is not excluded. Unfortunately for Land O'Lakes, there is no principled way to conclude that sugar occurring in milk is covered by the patent, but sugar occurring in corn syrup is not. We decline to hold that "sugar" also includes all products that happen to contain sugar.

n4 Land O'Lakes' product does not use sugar. Instead it uses corn syrup that contains sugar.

We have reviewed Land O'Lakes' other arguments on the issue of claim construction and find them without merit. Accordingly, we find no error and affirm the district court's claim construction.

D. Effective Filing Date

Land O'Lakes also cross-appeals alleging error in the district court's failure to find that the '670 patent has an effective filing date of November 21, 1994. We agree.

The '670 patent was based on a CIP application filed on November 21, 1994. See footnote 1, supra. The original application [**20] (the '803 application) was filed on June 1, 1992. The original application disclosed a coffee whitener that contains inter alia, 1-2% by weight of butterfat and 0.3-5% by weight of fat substitute. The '670 patent on the other hand requires 1-3.57% by weight of butterfat and 0.3-10% by weight of fat substitute.

[HN10] When one files a continuation-in-part application, "matter disclosed in the parent application is entitled to the benefit of the filing date of the parent application." Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558 (Fed. Cir. 1994). "Determination of whether a priority document contains sufficient disclosure under 35 U.S.C. § 112, first paragraph is a question of law." Id.

We have previously held that to decide whether a continuation-in-part application receives the benefit of an earlier filing date, "a court must examine whether the 'disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." Augustine Med. Inc., v. Gaymar Indus., Inc., 181 F.3d 1291, 1302 (Fed. Cir. 1999) (quoting Waldemar Link, 32 F.3d at 558). [**21]

Applying the above test, one cannot conclude that the '803 application provided sufficient disclosure for the matter claimed in the '670 patent. Nothing in the '803 application teaches or even hints at the possibility of using higher percentages of butterfat or fat substitute. In addition, Pordy fails to point to any evidence indicating that one of skill in the art would have understood the disclosure of the '803 application to suggest that the inventor, at that time, also had possession of the ranges claimed in the '670 patent. As a matter of law therefore, the '670 patent cannot claim the earlier filing date of the '803 application, and is thus limited to the filing date of November 21, 1994. Accordingly, we reverse the ruling of the district court denying Land O'Lakes motion for judgment as a matter of law on this issue.

The question remains, however, whether any products produced after June 1, 1992, but before November 21, 1994, would make the '670 patent anticipated, as claimed by Land O'Lakes. n5

n5 Land O'Lakes argues that Kemps' Coffee Right is one such product.

[*930] [**22]

[HN11] Anticipation is a question of fact. Merck & Co., Inc. v. Teva Pharms. USA, Inc., 347 F.3d 1367, 1369 (Fed. Cir. 2003). [HN12] A question of fact is initially best resolved by the district court. On remand, Land O'Lakes [HN13] must prove anticipation by "clear and convincing evidence." See State Contracting & Eng'g Corp. v. Condotte Am., Inc., 346 F.3d 1057, 1067 (Fed. Cir. 2003) [HN14] ("A party seeking to establish that particular claims are invalid must overcome the presumption of validity in 35 U.S.C. § 282 by clear and convincing evidence.") If Land O'Lakes succeeds in showing that Pordy's patent is anticipated, the patent is to be held invalid and judgment is to be entered for Land O'Lakes. Should Land O'Lakes fail to prove anticipation by clear and convincing evidence, Pordy is entitled to judgment and the damages awarded to him by the jury. See Moore's Federal Practice § 38.43[4][c] (3d ed. 2004) [HN15] ("The trial judge continues to be bound by a jury's finding even if its verdict is vacated, so long as the underlying factfinding is not impugned."); see also Artis v. Hitachi Zosen Clearing Inc., 967 F.2d 1132, 1138 (7th Cir. 1992) [**23] (same). For this reason, we vacate the jury verdict and remand the case to the district court for a new trial on the issue of anticipation. The district court is to reinstate the jury's verdict if Land O'Lakes fails to prove anticipation.

III. CONCLUSION

For the foregoing reasons, we affirm the district court's claim construction, and reverse on the issue of effective filing date. We vacate the JMOL and the jury verdict and remand the matter to the district court for a new trial limited to the issue of anticipation.

No costs.

EXHIBIT 20

Filed 09/15/2006

LEXSEE 2002 US APP LEXIS 16593

LAPORTE PIGMENTS, INC. (now Rockwood Pigments NA, Inc.) and CHEMISCHE WERKE BROCKHUES AG, Plaintiffs-Appellees, v. AXEL J., LP, AXEL J., LLC, AXEL J. CORPORATION, and AXEL E. JUNGK, Defendants-Appellants.

01-1226

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

44 Fed. Appx. 960; 2002 U.S. App. LEXIS 16593

August 15, 2002, Decided

NOTICE: [**1] RULES OF THE FEDERAL CIRCUIT COURT OF APPEALS MAY LIMIT CITATION TO UNPUBLISHED OPINIONS. PLEASE REFER TO THE RULES OF THE UNITED STATES COURT OF APPEALS FOR THIS CIRCUIT.

SUBSEQUENT HISTORY: Rehearing Denied September 25, 2002, Reported at: 2002 U.S. App. LEXIS 21336.

DISPOSITION: Affirmed.

CASE SUMMARY:

PROCEDURAL POSTURE: Defendant companies and individual (companies) appealed an order of the United States District Court for the Western District of Missouri, which denied their motion for judgment of noninfringement, or alternatively a new trial, in plaintiff patent owner's infringement action.

OVERVIEW: The patent was directed to a process for dyeing concrete. The claim at issue provided it was a process of dyeing concrete comprising mixing pigmentcontaining granules with cement, wherein each granule "consisting" essentially of at least one pigment selected from a group consisting of manganese oxide and iron oxide and of at least one binder for promoting the dispersal of the pigment in the concrete. The companies argued that the court improperly construed the term "binder" as requiring that it be more susceptible to shear forces than prior art granules, asserting that the specification did not support that interpretation and that a binder's susceptibility to shear was not necessarily related to its ability to promote dispersal. The instant court found the district court's limited interpretation of "binder" was harmless error. Nothing in the claim limited "binder" to materials that were either moisture-soluble or more susceptible to shear forces than prior art granules. The instant court construed "binder" as a material that promoted dispersal of the pigment in the concrete, subject to express disavowal during prosecution that it not contain hydraulic material.

OUTCOME: The district court's order was affirmed.

LexisNexis(R) Headnotes

Civil Procedure > Trials > Judgment as Matter of Law > General Overview

Civil Procedure > Appeals > Standards of Review > De Novo Review

[HN1] The court of appeals reviews a district court's denial of a motion for judgment as a matter of law without deference.

Civil Procedure > Trials > Judgment as Matter of Law > General Overview

[HN2] In determining whether to grant a motion for judgment as a matter of law, the court must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.

Civil Procedure > Judgments > Relief From Judgment > Motions for New Trials

Civil Procedure > Appeals > Standards of Review > Abuse of Discretion

[HN3] The court of appeals reviews the denial of a motion for a new trial for abuse of discretion.

Civil Procedure > Appeals > Standards of Review > De Novo Review

Patent Law > Jurisdiction & Review > Standards of Review > De Novo Review

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals

[HN4] Patent claim construction is an issue of law that the court of appeals reviews de novo.

Civil Procedure > Trials > Jury Trials > Province of Court & Jury

Patent Law > Infringement Actions > Doctrine of Equivalents > Fact & Law Issues

Patent Law > Infringement Actions > Infringing Acts > General Overview

[HN5] The determination of patent infringement, whether literal or under the doctrine of equivalents, is a question of fact.

Patent Law > Claims & Specifications > Claim Language > General Overview

[HN6] The absence of the term "means" in a patent claim creates a presumption that 36 U.S.C.S. § 112, para. 6, does not apply.

Patent Law > Claims & Specifications > Claim Language > General Overview

Patent Law > Claims & Specifications > Description Requirement > General Overview

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview

[HN7] Where patent claim language is clear, the court must accord it full breadth even if the result is a claim that is clearly invalid.

Patent Law > Ownership > Conveyances > Assignments Patent Law > Ownership > Conveyances > Assignor & Licensee Estoppel

[HN8] Assignor estoppel is an equitable doctrine that prevents one who has assigned the rights to a patent (or a patent application) from later contending that what was assigned is a nullity.

NEWMAN, LOURIE, and JUDGES: Before CLEVENGER, Circuit Judges.

OPINION BY: LOURIE

OPINION: [*961] LOURIE, Circuit Judge.

DECISION

Laporte II at 9.Axel J., LP; Axel J., LLC; Axel J. Corporation; and Axel E. Jungk (collectively, "Axel") appeal from the decision of the United States District Court for the Western District of Missouri denying Axel's motion for judgment of noninfringement as a matter of law or, in the alternative, for a new trial on that issue. Laporte Pigments, Inc. v. Axel J., LP, 2001 U.S. Dist. LEXIS 24461, No. 00-0329-CV-W-5, slip op. at 1 (W.D. Mo. Feb. 1, 2001) ("Laporte II"). Because the court properly determined that substantial evidence supports the jury's verdict of infringement and that Axel was not entitled to a new trial, we affirm.

DISCUSSION

The patent at issue, U.S. Patent 4,946,505, is directed to a process for dyeing concrete. Claim 1 of the '505 patent reads in relevant part: "A process of dyeing concrete comprising mixing pigment-containing granules with cement . . . wherein . . . each granule consisting [sic] essentially of at [**2] least one pigment selected from the group consisting of manganese oxide and iron oxide and of at least one binder for promoting the dispersal of the pigment in the concrete . . . " '505 patent, col. 7, Il. 12-23.

The inventor, Axel E. Jungk, who is one of the defendants in this action, assigned the invention to his employer, Chemische Werke Brockhues AG, which then granted an exclusive license to Laporte Pigments, Inc. (now Rockwood Pigments NA, Inc.). Laporte Pigments, Inc. v. Axel J., LP, 2000 U.S. Dist. LEXIS 22302, No. 00-0329-CV-W-5, slip op. at 1 (W.D. Mo. Aug. 18, 2000) ("Laporte I"). Dr. Jungk later left Brockhues and formed his own company, Axel J., LP, which manufactures pigment granules called AXEL 'SMARTLINS in Canada for sale to concrete manufacturers in the United States. Id. at 2. Those manufacturers then perform the process of mixing the granules with cement and water to form dyed concrete. Id.

Laporte sued Axel, claiming inducement of infringement of claim 1, and it filed a motion for a preliminary injunction to enjoin Axel from selling AXEL 'SMARTLINS. Id. In addressing the only contested claim limitation, the district court construed the "binder" limitation of claim [**3] 1 as requiring a "binder that promotes homogeneous pigment dispersal either by moisture-solubility, being more susceptible to shear forces than prior art granules, or both." Id. at 13. It then determined that Laporte had failed to establish a reasonable likelihood of success on the merits of its claim because Laporte had not persuasively shown that the Neocryl styrene/acrylic copolymer in AXEL 'SMARTLINS met the "binder" limitation as the court had construed it. Id. at 19. The court thus denied Laporte's motion for a preliminary injunction.

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Laporte later amended its complaint to accuse Axel of inducing infringement by its manufacture and sale of an additional product containing a K-702 binder, and the case proceeded to a jury trial. At trial, Laporte's expert explained that binders "hold" the pigment and then "release" [*962] it for homogeneous distribution. Laporte II at 6. At the close of all the evidence, Axel filed a motion for a directed verdict. In that document, Axel did not argue that Dr. Jungk's individual liability for inducing infringement should be distinguished from that of the other Axel defendants. Moreover, the instructions given to the jury did not distinguish [**4] liability among the various defendants. Following trial, the jury found for Laporte and determined that it was entitled to recover \$ 1.6 million in damages for the NeoCryl product and \$ 500,000 for the K-702 product.

Axel filed post-trial motions seeking judgment of noninfringement as a matter of law or, in the alternative, a new trial. The district court denied those motions with respect to Axel J., LP; Axel J. Corporation; and Dr. Jungk in his individual capacity. n1 The court determined that Laporte's expert had provided the jury with a sufficient "hold and release" theory of infringement to sustain the jury's verdict. The court was also not persuaded by Axel's arguments that Dr. Jungk was not individually liable for infringement, concluding that "the jury had ample evidence from which it could infer Jungk's intent to induce." Id. at 4. Axel timely appealed; we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

> nl The court granted Axel's motion for judgment as a matter of law with respect to Axel J., LLC.

[**5]

[HN1] We review a district court's denial of a motion for judgment as a matter of law without deference. Dawn Equip. Co. v. Ky. Farms Inc., 140 F.3d 1009, 1014, 46 U.S.P.Q.2D (BNA) 1109, 1111 (Fed. Cir. 1998). [HN2] In determining whether to grant a motion for judgment as a matter of law, "the court must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150, 147 L. Ed. 2d 105, 120 S. Ct. 2097 (2000). [HN3] We review the denial of a motion for a new trial for abuse of discretion. Biodex Corp. v. Loredan Biomedical, Inc., 946 F.2d 850, 854, 20 U.S.P.Q.2D (BNA) 1252, 1254-55 (Fed. Cir. 1991). [HN4] Claim construction is an issue of law, Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71, 34 U.S.P.Q.2D (BNA) 1321, 1322 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct.

1384 (1996), that we review de novo, Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456, 46 U.S.P.Q.2D (BNA) 1169, 1172 (Fed. Cir. 1998) (en banc). [HN5] The determination of infringement, whether literal or [**6] under the doctrine of equivalents, is a question of fact. Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353, 48 U.S.P.Q.2D (BNA) 1674, 1676 (Fed. Cir. 1998).

Filed 09/15/2006

On appeal, Axel argues that the court improperly construed the term "binder" as requiring that it be more susceptible to shear forces than prior art granules, asserting that the specification does not support that interpretation and that a binder's susceptibility to shear is not necessarily related to its ability to promote dispersal. Axel asserts that, under a proper interpretation of the claim, the NeoCryl and K-702 granules do not infringe the '505 patent because they do not promote dispersal of the pigment. Alternatively, Axel argues noninfringement on the ground that the term "binder" should be construed according to 35 U.S.C. § 112, P 6, because it is defined by its binding function, and that a broader construction of the term "binder" that is not limited to the specific embodiments in the specification would be invalid for indefiniteness or lack of enablement. Axel also contends that use of the K-702 granules does not [*963] infringe the patent because they contain hydraulic material that was specifically [**7] disclaimed during prosecution. Finally, Axel argues that the court erred in denying its motion for judgment as a matter of law that Dr. Jungk is not liable for inducing infringement in his individual capacity.

Laporte responds that the court properly interpreted a "binder" as a material that holds the pigment in granular form and then releases it either for chemical reasons relating to its moisture solubility or for mechanical reasons relating to its susceptibility to shear forces. Laporte asserts that substantial evidence supports the jury's verdict that both the NeoCryl and K-702 granules are "binders" under that construction of that term. Moreover, Laporte argues that § 112, P6, does not apply to the "binder" limitation because the claim does not recite any "means" and because the term "binder" denotes a material, and that Axel's allegations that a broader interpretation would be invalid are precluded by the doctrine of assignor estoppel. Laporte also responds that Dr. Jungk waived the issue of his individual liability by not raising it in his motion for a directed verdict at the close of all the evidence.

In the exercise of our plenary review of the court's claim construction, [**8] we disagree with the district court's limited interpretation of the term "binder" as being either moisture-soluble or more susceptible to shear forces than prior art granules. To the extent the court erred by interpreting the claim too narrowly, however, that error was harmless. The jury determined that Axel infringed the '505 patent even under the court's restricted interpretation and thus a fortiori would have arrived at the same conclusion under our broader construction.

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To begin, we look to the ordinary meaning of the claim, which is directed to "at least one binder for promoting the dispersal of the pigment in the concrete." '505 patent, col. 7, ll. 21-23. Nothing in the claim limits the term "binder" to materials that are either moisturesoluble or more susceptible to shear forces than prior art granules. The specification sets forth a significant number of appropriate materials that are exemplary of the claimed binders, but does not restrict the meaning of that term to those materials. Id. at col. 3, 11. 27-51.

The specification also discusses problems found with certain prior art granules used for dyeing concrete. In particular, it points out that the shear forces [**9] exerted during mixing have been insufficient to disperse those granules, id. at col. 2, 11, 27-29, and that the moisture content of the concrete and the time available for mixing were not always sufficient to dissolve bindercontaining pigment granules, id. at col. 2, 11. 42-44. Those statements concerning the properties of prior art granules apparently prompted the district court to construe the term "binder" as having properties different from binders used in the prior art. We disagree with that interpretation. The specification does not limit the term "binder" to exclude disadvantageous prior art granules, as a binder is but one of the components of the pigment granules used in the prior art. See, e.g., '505 patent, col. 7, Il. 19-23. The disadvantages of prior art granules or processes are not limitations on properties of the binders, which are defined in the claim only as having to promote the dispersal of the pigment in the concrete. Other components of the granules may contribute to the results of processes described in the prior art. Moreover, the claimed process for dyeing concrete has a number of other limitations not at issue on appeal that may be responsible [**10] for the alleged superior performance of the granules of the present [*964] process over the prior art. We therefore conclude that the specification does not compel the district court's construction of the claim term "binder."

We agree with the district court, however, that other intrinsic evidence does limit the proper interpretation of the term "binder." During prosecution, the examiner rejected the claims over a prior art reference that disclosed the use of cement or hydraulic (water-reactive) material as a binder. In response, the applicant amended the claim to add the language "consisting essentially of," which, the examiner explained in the notice of allowability, "eliminates the possibility of hydraulic material in the pigment-containing granule." Id. We therefore construe a "binder" as a material that promotes dispersal of the pigment in the concrete, subject to the express disavowal during prosecution that it not contain hydraulic material. See Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576, 34 U.S.P.Q.2D (BNA) 1673, 1676 (Fed. Cir. 1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation [**11] that was disclaimed during prosecution.").

We are not persuaded by Axel's arguments that the term "binder" should be construed according to 35 U.S.C. § 112, P 6. [HN6] The absence of the term "means" in the claim creates a presumption that § 112, P6, does not apply. Micro Chem., Inc. v. Great Plains Chem. Co., 194 F.3d 1250, 1257, 52 U.S.P.Q.2D (BNA) 1258, 1263 (Fed. Cir. 1999). Moreover, the term "binder" describes a material, as shown by the numerous suitable binder materials listed in the '505 patent specification at col. 3, 11. 33-51, that connotes structure to those skilled in the art. Consequently, the presumption against application of § 112, P 6 has not been overcome.

We are also not persuaded by Axel's arguments that the term "binder" must be construed narrowly in order to preserve the validity of claim 1. The clear language of the claim and the intrinsic evidence support a broad interpretation of that term and we therefore accord the term "binder" its full breadth, even if invalidity issues could be raised as a result of that broad construction. See Tate Access Floors, Inc. v. Interface Architectural Resources, Inc., 279 F.3d 1357, 1372, 61 U.S.P.Q.2D (BNA) 1647, 1658 (Fed. Cir. 2002) [**12] [HN7] ("Where claim language is clear we must accord it full breadth even if the result is a claim that is clearly invalid.") (citations omitted). In any event, we cannot consider the validity of the claim, as Axel is estopped from asserting the invalidity of the patent that Dr. Jungk previously assigned to Brockhues. See Diamond Scientific v. Ambico, Inc., 848 F.2d 1220, 1224, 6 U.S.P.Q.2D (BNA) 2028, 2030 (Fed. Cir. 1988) [HN8] ("Assignor estoppel is an equitable doctrine that prevents one who has assigned the rights to a patent (or a patent application) from later contending that what was assigned is a nullity.").

Turning next to infringement, we find no error in the district court's judgment that substantial evidence supports the jury's verdict of infringement, even under the claim construction we have adopted that is in part different from the district court's. Laporte presented expert testimony that the accused granules containing NeoCryl and K-702 binders promote dispersion of the pigment in the concrete. As Laporte's photographic exhibits make vividly clear, the accused binders discretely hold the pigment particles until subjected to mixing with water, whereupon the concrete is [**13] homogenously dyed. We are also not persuaded by Axel's arguments that the K-702 granules contain hydraulic material and are therefore outside [*965] the scope of the claim. Hydraulic material is material that will react with water, not mate44 Fed. Appx. 960, *; 2002 U.S. App. LEXIS 16593, **

rial that is fully hydrated. Laporte presented evidence that the K-702 granules were fully hydrated and thus would not have contained any hydraulic material, and the jury was entitled to rely upon that evidence in reaching its verdict. In denying Axel's motion for judgment as a matter of law, the district court properly drew all reasonable inferences in favor of Laporte and declined Axel's invitation to reweigh the evidence and substitute its credibility determinations for the jury's. See Reeves, 530 U.S. at 150. We therefore conclude that the district court did not err in denying that motion.

We decline to address Axel's arguments concerning Dr. Jungk's individual liability for inducing infringement. Axel failed to move for a directed verdict on that issue at the close of all the evidence, and we agree with Laporte that Axel thereby waived that issue. We apply the law of the regional circuit to the procedural question of waiver, as it [**14] does not uniquely pertain to patent law. See Midwest Indus., Inc. v. Karavan Trailers, Inc., 175 F.3d 1356, 1359, 50 U.S.P.Q.2D (BNA) 1672, 1675 (Fed. Cir. 1999) (en banc in relevant part). In the Eighth Circuit, such failure necessarily precludes a party from moving for judgment as a matter of law on the issue not previously raised. See Fed. R. Civ. P. 50(a), (b); Hubbard v. White, 755 F.2d 692, 695-96 (8th Cir. 1985). Moreover, Axel failed to object to the jury instructions, which did not distinguish liability among the various defendants, and we decline to cure that deficiency on appeal in the absence of plain error. See Horstmyer v. Black & Decker, (U.S.), Inc., 151 F.3d 765, 771 (8th Cir. 1998).

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Finally, we conclude that Axel has not persuasively demonstrated on appeal that the district court abused its discretion in denying Axel's motion for a new trial on the issues of infringement and Dr. Jungk's individual liability. For the foregoing reasons, we affirm the district court's denial of Axel's motion for judgment as a matter of law or a new trial.

EXHIBIT 21

LEXSEE 1994 U.S. APP. LEXIS 36261

OSCAR MAYER FOODS CORPORATION, Plaintiff-Appellee, v. CONAGRA, INC., Defendant-Appellant, and SWIFT-ECKRICH, INC., Defendant.

Nos. 94-1247, 94-1248

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

1994 U.S. App. LEXIS 36261; 35 U.S.P.Q.2D (BNA) 1278

December 22, 1994, DECIDED

NOTICE: [*1] **RULE** 47.6(b). NONPRECEDENTIAL OPINIONS AND ORDERS. AND **ORDERS** WHICH OPINIONS DESIGNATED AS NOT CITABLE AS PRECEDENT ARE THOSE UNANIMOUSLY DETERMINED BY THE PANEL AT THE TIME OF THEIR ISSUANCE AS NOT ADDING SIGNIFICANTLY TO THE BODY OF LAW. OPINIONS AND ORDERS DESIGNATED SHALL NOT BE EMPLOYED OR CITED AS PRECEDENT. THIS RULE DOES NOT PRECLUDE ASSERTION OF ISSUES OF CLAIM PRECLUSION, ISSUE PRECLUSION, JUDICIAL ESTOPPEL, LAW OF THE CASE OR THE LIKE BASED ON A DECISION OF THE COURT RENDERED IN A NONPRECEDENTIAL OPINION AND ORDER.

SUBSEQUENT HISTORY: Rehearing Denied and In Banc Suggestion Declined January 31, 1995, Reported at: 1995 U.S. App. LEXIS 2505. Reported in Table Case Format at: 45 F.3d 443, 1994 U.S. App. LEXIS 40213.

DISPOSITION: Affirmed

JUDGES: Before MICHEL, Circuit Judge, BENNETT, Senior Circuit Judge, and RADER, Circuit Judge.

OPINION BY: BENNETT

OPINION: BENNETT, Senior Circuit Judge.

ConAgra, Inc. (ConAgra) appeals from a judgment entered against it on a jury verdict in favor of Oscar Mayer Foods Corporation (OMFC). Oscar Mayer Foods Corp. v. ConAgra, Inc., 1994 U.S. Dist. LEXIS 4018, 31 USPQ2d 1173 (W.D. Wis. 1994). The jury found that ConAgra had infringed OMFC's patents and that Con-Agra failed to prove clearly and convincingly facts supporting its contention that OMFC's patents are invalid. For the reasons set forth below, we affirm.

BACKGROUND [*2]

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OMFC sued ConAgra for infringing two patents, both of which pertain to preserving food products. In particular, both patents teach that adding a lactate salt in an amount from 1% to 7% by weight to cooked (but not sterilized), anaerobically packaged, uncured fish or poultry may help prevent botulism. OMFC's U.S. Patent 4,789,729 (the '729 patent), which issued in 1989, claims a process. OMFC's U.S. Patent 5,017,391 (the '391 patent), which issued in 1991, claims foodstuffs made by the process. Both patents take their filing dates from the same application, filed in December 1985.

Botulism is a serious, potentially fatal form of food poisoning caused by the bacteria Clostridium botulinum (C. bot.). The bacteria has both a dormant state and a vegetative state. In its vegetative state C. bot. produces the toxin which causes botulism. Botulism is extremely rare, requiring the concurrence of several conditions. Because C. bot. grows only in the absence of oxygen, food must be anaerobically packaged for botulism to occur. The food must have an appropriate pH level. The food must be sufficiently moist. The food must be stored at a sufficiently high temperature. Even where C. [*3] bot. has entered its vegetative state, cooking the food before it is eaten breaks down the toxin.

The Patents in Suit

The broadest claim of the '729 patent for OMFC's process reads:

> 1. A method for delaying Clostridium botulinum growth in a foodstuff selected from the group consisting of fish and poultry, the method consisting essentially of:

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(a) adding a lactate slat [sic] to a fresh foodstuff selected from the group consisting of fish and poultry, said lactate salt being added in an amount of about 1% to about 7%;

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- (b) cooking the foodstuff at high humidity to a temperature sufficient to cook the foodstuff but not sufficient to sterilize the foodstuff:
 - (c) cooling the cooked foodstuff; and
- (d) packaging the cooked foodstuff in a plastic barrier package.

Claim one of the '391 patent, which is the broadest of OMFC's product claims, reads:

> 1. In a packaged foodstuff, said foodstuff being selected from the group consisting of fish and poultry, said fish or poultry being cooked, but not sterilized, being packaged in an anaerobic plastic barrier package and intended to be stored under refrigeration, said foodstuff being subject to the growth of Clostridium botulinum under [*4] temperature abuse, the improvement wherein the foodstuff comprises a lactate salt in an amount of from 1 to 7% by weight and sufficient to delay growth of Clostridium botulinum in the foodstuff.

The District Court Proceedings

OMFC filed an infringement suit against ConAgra in the United States District Court for the Western District of Wisconsin. In a pretrial motion, ConAgra asked the court to rule that a process which includes a second salt such as sodium chloride or sodium tripolyphosphate does not infringe the '729 patent. The motion was denied.

At the close of OMFC's case-in-chief, ConAgra moved for judgment as a matter of law (JMOL), arguing that even if every other limitation were met OMFC had nonetheless failed to prove that ConAgra used the process of the '729 patent for the purpose of inhibiting the growth of C. bot. After this motion was denied, ConAgra noted that when inquiring into validity the court would have to use the same construction as had been adopted for infringement. ConAgra argued that therefore the inventors' intent in using sodium lactate could not be considered when determining obviousness.

ConAgra sought to introduce evidence that in its process [*5] a second salt (either sodium chloride or sodium tripolyphosphate) reacted synergistically with sodium lactate to produce unexpectedly good results. The district court excluded this evidence, and later charged the jury over ConAgra's objection that the use of table salt in the accused process did not affect the basic and novel characteristics of the claimed process.

ConAgra urged the court to submit the case to the jury by means of an elaborate special verdict form. The court declined, relying instead on jury instructions. Con-Agra objected to the instructions on obviousness and damages, as well as to the instruction regarding the use of a second salt in the process. The jury returned a verdict in favor of OMFC. The court denied ConAgra's post trial renewal of its JMOL motion and its motion for a new trial. This appeal followed.

DISCUSSION

Standard of Review

ConAgra ascribes several errors to the trial court. It argues that the court misstated the law in its jury instructions and that it should have used a special verdict form. It argues that the trial court should have granted its renewed motion for JMOL. Finally, ConAgra argues that the trial court should have granted its [*6] motion for a new trial.

In reviewing the trial court's judgment, this court examines the content of jury instructions for prejudicial legal error. Delta-X Corp. v. Baker Hughes Prod. Tools, Inc., 984 F.2d 410, 415, 25 USPO2d 1447, 1450 (Fed. Cir. 1993). A new trial will be ordered only when errors in the instructions as a whole clearly misled the jury. Delta-X, 984 F.2d at 415, 25 USPQ2d at 1450-51. To succeed, ConAgra must show (1) that the jury instructions, read in their entirety, were incorrect and (2) that it requested instructions which could have eliminated the error. Id., 984 F.2d at 415, 25 USPQ2d at 1451; Goodwall Constr. Co. v. Beers Constr. Co., 991 F.2d 751, 755, 26 USPO2d 1420, 1423 (Fed. Cir. 1993). Regarding the form of the instructions, this court will reverse a judgment only if the trial court abused its discretion when selecting the manner in which to submit a case to the jury. Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506, 1515, 220 USPQ 929, 938 [*7] (Fed. Cir.), cert. denied, 469 U.S. 871, 83 L. Ed. 2d 150, 105 S. Ct. 220 (1984).

When an appellant contests the denial of a renewed motion for JMOL, this court presumes that, on issues of law with underlying issues of fact, the jury made the proper findings necessary to support its verdict. Shearing v. Iolab Corp., 975 F.2d 1541, 1544, 24 USPQ2d 1133, 1136 (Fed. Cir. 1992). The jury expressly found that ConAgra infringed OMFC's patents. To succeed on appeal, ConAgra must prove (1) that the jury's findings, whether presumed or express, are not supported by substantial evidence or (2) the facts properly found cannot support the jury's verdict. Mentor Corp. v. Coloplast,

Inc., 998 F.2d 992, 994, 27 USPQ2d 1521, 1524 (Fed. Cir. 1993); Wang Lab., Inc. v. Toshiba Corp., 993 F.2d 858, 863, 26 USPQ2d 1767, 1772 (Fed. Cir. 1993); Standard Havens Prods. v. Gencor Indus., 953 F.2d 1360, 1367, 21 USPQ2d 1321, 1326 (Fed. Cir. 1991), cert. denied, 121 L. Ed. 2d 28, 113 S. Ct. 60 (1992). [*8] A finding is supported by substantial evidence if a reasonable juror could have made that finding upon considering the record as a whole. Wang, 993 F.2d at 863, 26 USPQ2d at 1772; Shearing, 975 F.2d at 1544, 24 USPQ2d at 1136; Standard Havens, 953 F.2d at 1367, 21 USPQ2d at 1326. The grant of a new trial is committed to the discretion of the trial court, which will be affirmed absent an abuse of discretion. Shearing, 975 F.2d at 1544, 24 USPQ2d at 1136; Standard Havens, 953 F.2d at 1367, 21 USPQ2d at 1326.

Obviousness

1. Jury Instructions.

ConAgra argues that the trial court misstated the law of obviousness in its jury charge. A patent is invalid if the claimed subject matter would have been obvious to one of ordinary skill in the art at the time of invention. 35 U.S.C. § 103 (1988). Obviousness is a question of law with four factual predicates: the scope and content of the prior art, the differences between the subject [*9] matter claimed and the prior art, the level of ordinary skill in the art, and other objective indicia of nonobviousness such as commercial success, long felt but unsolved need, and acquiescence of others in the industry to the patent's validity. Graham v. John Deere Co., 383 U.S. 1, 17-18, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966).

ConAgra argues that OMFC's contribution to the art was objectively obvious. Per ConAgra, it would have been obvious to one of ordinary skill in the art to use sodium lactate as one possible solution to certain problems other than preventing botulism, such as shortness of shelf life. ConAgra contends that it is impermissible to consider an inventor's subjective purpose when determining whether claimed subject matter is obvious. Contrary to ConAgra's position, however, the problem an inventor professes to have solved is relevant in framing the obviousness inquiry.

ConAgra cites many cases for the proposition that discovering a new use for an old product does not entitle an inventor to a patent on the old product. E.g., *In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990);* [*10] *Titanium Metals Corp. v. Banner, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985).* Although certainly true, that principle is inapplicable here. The novelty of the subject matter OMFC claimed was not an issue at trial. If the subject matter were old, OMFC could not now withdraw from the public domain that which was already in actual use merely

because it discovered a new, additional use. The obviousness, however, of subject matter not now in use raises different concerns. A step that supplies an obvious, but perhaps impractical, solution to one problem may well provide a new, unexpected, and nonobvious solution to a different problem. The difference lies in the stated utility of the invention, i.e., the problem an applicant claims to have solved.

ConAgra argues that merely identifying a new purpose is not sufficient to overcome a prima facie case of obviousness, citing In re Dillon, 919 F.2d 688, 693-94, 16 USPQ2d 1897, 1902 (Fed. Cir. 1990). Prima facie obviousness is a procedural tool employed in ex parte proceedings before the PTO. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). [*11] In litigation, an issued patent is presumed valid. 35 U.S.C. § 282 (1988). Because of this presumption, the party opposing validity in litigation bears the burden both of proving by clear and convincing evidence facts establishing invalidity and also of coming forward with evidence to make out a prima facie case of obviousness. Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 291-92, 227 USPQ 657, 662-63 (Fed. Cir. 1985). Because no statutory presumption of validity attaches during prosecution, it is far from clear that the requirements of a prima facie case were the same in Dillon as in Ashland. Even if prima facie obviousness as described in Dillon is sufficient to establish a prima facie case of obviousness in litigation as required under Ashland, the prior art cited by ConAgra and reviewed below was inadequate to establish such prima facie obvious-

ConAgra also contends that, even if an inventor's purpose is relevant, the inventors in the case at bar did not set about to discover a method of inhibiting the growth of C. bot. It does not matter, however, [*12] what motivated an inventor to discover the claimed subject matter. The discovery may be by design, by accident, by a vision in a dream, by a sudden flash of genius, or by any other conceivable means. "Patentability shall not be negatived by the manner in which the invention was made." 35 U.S.C. § 103 (1988). The relevant consideration is the problem the patent applicant purports to have solved, regardless of the technique employed to achieve that solution. OMFC professes to have solved the problem of delaying the growth of C. bot. in anaerobically packaged, precooked, unsterilized, uncured poultry and fish products. Its patent is invalid if its solution to that problem would have been obvious to one of ordinary skill in the art.

The nature of the problem solved affects all of the four factual inquiries underlying obviousness. Prior art is relevant to the obviousness inquiry if it is analogous, i.e., if it is drawn from that inventor's field of endeavor or if it

is "reasonably pertinent to the particular problem with which the inventor is involved." In re Paulsen, 30 F.3d 1475, 1481, 31 USPQ2d 1671, 1676 (Fed. Cir. 1994) [*13] (emphasis added); Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., 21 F.3d 1068, 1072, 30 USPQ2d 1377, 1379 (Fed. Cir. 1994); Wang, 993 F.2d at 864, 26 USPO2d at 1773; In re Clay, 966 F.2d 656, 658, 23 USPQ2d 1058, 1060 (Fed. Cir. 1992). Because the problem affects the definition of the prior art, it therefore affects each of the first three Graham factors: the prior art's scope and content, the art's level of ordinary skill, and the prior art's differences from the claimed invention. See Graham, 383 U.S. at 17. Also, objective indicia of nonobviousness are helpful only where there exists a nexus between the indicia and the patented invention. For example, the failure of others is probative only if they sought to overcome the problem the applicant claims to have solved. Similarly, commercial success is probative only if it reflects a demand for that inventor's solution to the problem, not a response to marketing efforts or an effect of some other cause.

ConAgra requested [*14] the district court to charge the jury that the inventors' purpose in adding lactate salts to the foodstuff was irrelevant when determining validity. As shown above, such an instruction would have been misleading. The problem the inventors in their application claim to have solved is relevant to the obviousness inquiry. We discern no prejudicial legal error in the trial court's jury instructions. ConAgra also argues that the trial court should have used special verdict forms instead of instructions with a general verdict form. Even if this court finds interrogatories and special verdicts particularly useful when reviewing the question of obviousness, see ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT 404 (3d ed. 1994), the trial court did not here abuse its discretion, see Railroad Dynamics, 727 F.2d at 1515, 220 USPQ at 938 (discussing the standard of review), by submitting the case on a general verdict.

2. The Prior Art.

In addition to its arguments concerning the significance of motive, ConAgra also argues that OMFC's patent would have been obvious over the prior art presented at trial. Substantial evidence supported the implicit [*15] finding that, given the level of ordinary skill in the art, the claimed invention differed significantly from the prior art of pertinent scope and content. The references on which ConAgra relied most heavily are briefly considered below.

The first is a patent which teaches that washing raw foods in an aqueous sterilizing agent that may include sodium lactate will kill microorganisms which cause food poisoning. Ueno, U.S. Patent 4,592,892. That patent teaches contacting the surface of the foodstuff with a solution. Any addition of sodium lactate to the foodstuff itself is incidental and unmentioned. ConAgra admits that the foods in Ueno are cooked before being eaten. Thus, there was not even the potential for botulism. Ueno does not teach or suggest that adding sodium lactate to precooked, anaerobically packaged foods will inhibit the growth of C. bot.

ConAgra also relies on an unexamined Japanese application which discloses that sodium lactate enhances glycine's preservative properties against rope and slime bacteria without producing the undesirable side effects of browning or affecting flavor. Fukui, Kokai Tokkyo Koho Pub. No. 59-175870 (Published Oct. 4, 1984). Fukui teaches [*16] nothing about the effect of sodium lactate in an anaerobic environment. Indeed, Fukui reports generally unfavorable results from the use of sodium lactate without glycine.

ConAgra's next reference is a 1971 article by Dr. Angersbach which teaches the effect of sodium lactate on three types of bacteria. This report does not concern anaerobic bacteria such as C. bot. and teaches nothing about the effects of sodium lactate in poultry or fish. ConAgra also points to certain proceedings before the Food and Drug Administration. GRAS Status of Lactic Acid and Calcium Lactate, 49 Fed. Reg. 35366-67 (1984); Purac Inc.; Filing Petition For Affirmation Of GRAS Status, 50 Fed. Reg. 6252 (1985). Neither of these references teaches the use of sodium lactate to combat C. bot. in poultry or fish. Similarly, the advertisements by Purac, Inc. (Purac) to which ConAgra refers teach nothing about the use of sodium lactate to inhibit the growth of C. bot.

Dr. Diebel, OMFC's witness, testified that aerobic bacteria such as those discussed in Fukui and the article by Angersbach differ markedly from C. bot. Given these shortcomings [*17] of the prior art, the jury's findings implicit in its conclusion regarding obviousness are supported by substantial evidence. The trial court therefore properly denied ConAgra's renewal of its motion for JMOL on this issue. Likewise, the trial court did not abuse its discretion in denying ConAgra's motion for a new trial.

Infringement

ConAgra argues that the trial court mistakenly excluded evidence concerning the use of a second salt in the claimed process and that the trial court erred in charging the jury that the use of sodium chloride would not affect the basic and novel characteristics of the claimed invention. The determination of infringement is a two-step analysis. Electro Medical Sys., S.A. v. Cooper Life Sciences, 34 F.3d 1048, 1053, 32 USPQ2d 1017, 1020 (Fed. Cir. 1994). First, the patent claims must be properly interpreted without reference to the accused process. Id. This step poses a question of law which we review de novo. Id. Next, the accused process must be compared to the properly interpreted claims. Id. This second step poses a question of fact, which on a jury verdict we review under the substantial [*18] evidence standard. Id. The process claim of the '729 patent employed the transitional phrase "consisting essentially of." This phrase denotes a partially closed claim. A process which includes additional features that are not limitations of a partially closed claim will infringe that claim unless the additional features materially affect the basic and novel characteristics of the claimed process. Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1573-74, 224 USPQ 409, 412 (Fed. Cir. 1984); In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).

ConAgra argued at trial that OMFC had amended its claim to recite a partially closed transition phrase in order to overcome a prior art rejection which included the use of a second salt. ConAgra further contends that OMFC is thereby estopped from now arguing that its claim reads on processes that include a second salt. The question presented is whether the accused process literally infringes the claim. Because the issue is literal infringement, not the doctrine of equivalents, the doctrine of prosecution history estoppel [*19] is inapplicable. Black & Decker, Inc. v. Hoover Service Center, 886 F.2d 1285, 1295, 12 USPQ2d 1250, 1259 (Fed. Cir. 1989).

Nonetheless, the prosecution history may be used as an aid in interpreting the claims. Zenith Lab. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1421, 30 USPQ2d 1285, 1288 (Fed. Cir.), cert. denied, 130 L. Ed. 2d 409, 63 U.S.L.W. 3370 (U.S. 1994). The trial court, however, concluded that the use of the partially closed transition language was not intended to exclude all processes which use a second salt. That conclusion was not in error. During prosecution, OMFC distinguished the prior art two-salt process from the claimed subject matter on the grounds that all the prior art processes reduced the moisture content and the pH of the food. Thus, OMFC used a partially closed transitional phrase to exclude processes which reduce moisture and lower the pH of the foodstuff, not to exclude processes which use a second salt.

OMFC contends that ConAgra is judicially estopped from arguing that the interpretation of this claim of the '729 [*20] patent raises a question of fact, because (1) ConAgra had previously argued that the claim could be interpreted as a matter of law and (2) the trial court did indeed interpret the claim as a matter of law. Judicial estoppel is a procedural matter, reviewed under the law of the regional circuit in which the trial court sits. Water Technologies Corp. v. Calco, Ltd., 850 F.2d 660, 665 &

n.4, 7 USPQ2d 1097, 1101 & n.4 (Fed. Cir.), cert. denied, 488 U.S. 968, 102 L. Ed. 2d 534, 109 S. Ct. 498 (1988). Judicial estoppel in the Seventh Circuit has two elements: (1) that the party has previously taken a position that the court has adopted and (2) that the party is now asserting an inconsistent position. In re Cassidy, 892 F.2d 637, 641 (7th Cir.), cert. denied, 498 U.S. 812, 112 L. Ed. 2d 24, 111 S. Ct. 48 (1990). More particularly with respect to the first element, this court has previously noted that the party against whom estoppel is being asserted must have received some benefit from its previous [*21] position, i.e., it "won." Water, 850 F.2d at 665, 7 USPQ2d at 1101. Judicial estoppel does not apply here because the trial court rejected the claim interpretation ConAgra advanced. A party will often argue that facts material to a particular legal theory are not genuinely disputed. If the court rejects that theory, as it did here, the same party is free to argue that the facts material to a different legal theory are genuinely disputed. Because ConAgra did not prevail regarding claim interpretation, it is not estopped from arguing that genuine issues of fact exist.

Nonetheless, the trial court concluded, and we agree, that the basic and novel characteristic of this invention is the use of lactate salt to inhibit the growth of *C. bot*. Any additional step which does not interfere with the use of the lactate salt to inhibit the growth of *C. bot*. does not materially affect the basic and novel characteristics of the claimed invention and does not escape infringement. ConAgra's evidence did not suggest that the addition of a second salt interfered with the use of a lactate salt to suppress the growth of *C. bot*. Therefore, there [*22] was no factual issue to submit to the jury. The trial court committed no prejudicial legal error in its instructions to the jury regarding infringement. Substantial evidence supported the jury's verdict, and the trial court did not abuse its discretion in refusing to grant a new trial.

Damages

OMFC licensed Purac under the patents. OMFC reserved the right to practice the invention itself, but agreed not to license anyone else. Purac agreed to sublicense all who made reasonable offers. OMFC received a fixed royalty on each sublicense. ConAgra argues that, by this agreement, OMFC has bargained away any right to exclude others, retaining only the right to collect a royalty. ConAgra further argues that by giving this license, OMFC established the measure of damages for infringement at the fixed royalty rate OMFC received from Purac's sublicensees.

One who chooses not to accept a license that is offered may not thereafter rely on the license royalty rate as the measure of damages. See *Beatrice Foods Co. v. New England Printing & Lithographing Co.*, 899 F.2d

1171, 1173, 14 USPQ2d 1020, 1022 (Fed. Cir. 1990). ConAgra here chose not to accept [*23] the license offered to it by Purac. ConAgra may not rely on that license now to limit OMFC's recovery. ConAgra was neither a party to the contract between Purac and OMFC nor an intended beneficiary thereof. In the contract, OMFC explicitly retained the right to pursue its full range of infringement remedies against anyone who did not obtain a sublicense. The allocation of rights between OMFC and Purac does not limit ConAgra's liability.

The methodology for the computation of damages lies within the discretion of the trial court. State Indus., Inc. v. Mor-Flo Indus., Inc., 883 F.2d 1573, 1576-77, 12 USPQ2d 1026, 1028 (Fed. Cir. 1989), cert. denied, 493 U.S. 1022 (1990); King Instrument Corp. v. Otari Corp., 767 F.2d 853, 863, 226 USPQ 402, 409 (Fed. Cir. 1985), cert. denied, 475 U.S. 1016, 89 L. Ed. 2d 312, 106 S. Ct. 1197 (1986). The amount awarded must be sufficient to compensate the patent owner for his loss, and may not be less than a reasonable royalty. 35 U.S.C. § 284 [*24] (1988); State, 883 F.2d at 1577, 12 USPQ2d at 1028. Because OMFC retained the right to use the patented process, ConAgra's infringing activity was in direct competition with OMFC's sales. To the extent OMFC can satisfy the requirements for recovering lost profits, it is therefore entitled to recoup such damages. The trial court committed no prejudicial legal error in charging the jury that it could award lost profits despite the presence of the Purac license.

To recover lost profits, OMFC must prove that but for the infringement it would have made ConAgra's sales; however, OMFC need not eliminate all possibility that a purchaser would have bought a different product or forgone the purchase entirely. State, 883 F.2d at 1577, 12 USPQ2d at 1028. To satisfy this burden, it is sufficient to show four elements: (1) demand for products covered by the patent, (2) an absence of acceptable, noninfringing substitutes, (3) manufacturing ability and marketing capacity to exploit the demand, and (4) the amount of profits that would have been made. Id.; Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d

1152, 1156, 197 USPQ 726, 730 (6th Cir. 1978). [*25] Although this court has approved that approach, it is not the only way in which a plaintiff may prove lost profits. State, 883 F.2d at 1577, 12 USPQ2d at 1028.

With regard to the second Panduit element, this court has previously approved proof of market share as a substitute for proving the absence of acceptable, noninfringing alternatives. BIC Leisure Prods. v. Windsurfing Int'l, 1 F.3d 1214, 1219, 27 USPQ2d 1671, 1675 (Fed. Cir. 1993); State, 883 F.2d at 1577-78, 12 USPQ2d at 1029. The trial court correctly charged the jury that in order to award lost profits it must find that but for the infringement the patent owner would have made its market share of the infringer's sales. With regard to acceptable, noninfringing alternatives, the court correctly charged that the plaintiff bears the burden of proving its market share by a preponderance of the evidence. Con-Agra argues that in applying this instruction the jury was apt to ignore ConAgra's evidence that it could compete in this market without infringing the patent. We do not understand the [*26] instructions to invite such an interpretation. The trial court did not commit prejudicial legal error in charging the jury regarding lost profits. Substantial evidence supports the jury's finding of the appropriate market share, implicit in its award of damages. We will not disturb that finding.

CONCLUSION

In conclusion, we find no error in the district court's judgment. The instructions concerning obviousness were not incorrect. The trial court did not err in excluding evidence concerning ConAgra's use of a second salt in its process. The license between Purac and OMFC does not affect ConAgra's liability for infringement in this suit. The court's instructions regarding lost profits as the measure of damages were not in error. Substantial evidence supported the jury verdict on each of these points, and the district court did not abuse its discretion when it refused to order a new trial. The judgment of the district court is therefore affirmed.

EXHIBIT 22

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                IN THE UNITED STATES DISTRICT COURT
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                 FOR THE DISTRICT OF MASSACHUSETTS
 3
 4
    DEPUY MITEK, INC., a Massachusetts )
    Corporation,
 6
                        Plaintiff,
                                         ) Civil Action
 7
    v.
                                            No. 04-12457 PBS
 8
    ARTHREX, INC., a Delaware
 9
    Corporation,
10
                     Defendant.
11
              VIDEO DEPOSITION OF STEPHEN A. SOFFEN
12
13
                        Washington, D.C
14
                   Wednesday, January
                                       4, 2006
15
    The videotaped deposition of STEPHEN A. SOFFEN was
16
    convened on Wednesday, January 4, 2006, commencing
17
    at 9:03 a.m., at the offices of Dickstein Shapiro
18
    Morin & Oshinsky LLP, 2101 L Street, Northwest,
19
20
    Washington, D.C., before Cynthia R. Simmons Ott,
    Registered Merit Reporter, Certified Realtime
21
22
    Reporter, and Notary Public.
23
24
25
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1 from each prototype suture lot that they make, 2 so they still had the sample, and we can 3 collect it when we're in England next week, and 4 maybe that's, maybe that is the way to do it.

5 MR. TAMBURO: I'll contact him. If he has it, we'll get it to you.

MS. MALINOSKI: Yeah, he said at the deposition that he has it.

MR. TAMBURO: He may have been 10 mistaken. We'll check, we'll double-check.

11 12 pretty certain they had it.

13 BY MS. MALINOSKI:

O. Now, in the first page of Exhibit 116,

15 your February letter to Rich Skula, in the

16 second paragraph, you talk about the point of

17 novelty expressed in the Hunter patent. Do you 17 lot more to the patent than just that. I mean, 18 see that?

19 A. Yes.

O. Are you using point of novelty there 20

21 the same as basic and novel characteristics?

A. I think so, yes. That's the same

23 word, "novelty" and "novel characteristics," so

24 I believe so, yes.

25 And what is, what's the legal support

216 1 in the claim, that's going to trump or override anything to the contrary in the specification.

And I don't think there is anything to 4 the contrary in the specification, actually, as 5 I've testified earlier, but Rich did, and so

6 that's what I'm trying to say there.

O. So it's your opinion that adding 8 consisting essentially of to the claims

precludes the use of a coating, even though the 10 specification specifically contemplates that a

MS. MALINOSKI: He was pretty, he wasl 1 coating may optionally be used to further

enhance the properties of the braided suture?

MR. TAMBURO: Objection, 13

14 mischaracterizes the patent and the testimony.

THE WITNESS: Yeah, we've gone over 15 16 that issue sort of ad nauseam, but there's a

18 if that's all there was, the patent has a

19 specific disclaimer or denigration of coatings, 20 and that's what it controls. So I don't think

21 the specification is inconsistent with the

22 claim.

23 I think they work together, and the

24 statement that there's an option to add

25 coating, to "further improve," I think that's

215

1 for your statement in the next sentence that,

2 "The statement in column 6 of the Hunter patent

3 specification regarding the option of adding a

4 coating 'to further improve the handleability

5 and knot tiedown performance of the braid' is

6 trumped by the amendment that was made during

7 prosecution in response to a rejection when

8 they added the consisting essentially of

9 language"?

A. Right. What I was saying here is

11 that, certainly, we look to the specification

12 to interpret the claims of the patent, but the

13 first thing you do before you do anything else

14 is you look at the claim of the patent, and the

15 language of the claim controls or trumps, you

16 know, if there's something -- the spec can go

17 all over the place.

18

And there could be inconsistencies

19 between the specs, the specifications of a

20 patent and the claims, the claims, particularly

21 claims that have been specifically amended to

22 add something, that limitation is going to be

23 strictly construed, and that's what I was

24 saying here, that since consisting essentially

25 of, you know, was added by amendment and it's

1 the key word, only is of no moment. It's not

2 inconsistent with the claim, it's gratuitous,

3 it's what's in the prior art, and certainly,

4 that's, that's what the patent is all about.

5 The patent is all about improving handleability

6 without coating.

7 BY MS. MALINOSKI:

O. Isn't the patent directed to improving

9 the handleability of sutures without

10 sacrificing strength?

A. I think it's, I think that's --11

MR. TAMBURO: Objection to the form 12

13 and mischaracterizes the patent.

14

15 BY MS. MALINOSKI:

Q. I'm asking, isn't it. 16

A. Isn't it? The statement that you're, 17

18 that I think you're referring to in the patent

19 in column 2 talks about improving handling,

20 handling properties without sacrificing

21 physical strength, so, again, this goes back to

22 improving handling properties, which is, I

23 think, the key phrase.

24 And, I mean, you can obviously improve

25 handling with a smaller, you know, for

217

218 1 instance, with a smaller sized suture. I mean. 2 it's going to bend better. It's going to be 3 more pliable. But you're obviously going to

4 affect the strength of the suture there, so 5 what they're saying is, and you can also

6 improve handleability by adding coating, for 7 instance, and I don't know what effect that has

8 on strength.

It can have, I guess it can have some 10 effect on strength. But their point here was 11 that, that they wanted to improve handleability

12 without using a coating, and that's the way I

13 read the patent, so I differ with that

14 interpretation you just gave.

Q. Okay. So your, because the documents 15 16 are not very clear on this, your testimony is

17 that the novel and basic characteristic of the

18 invention is improving the handleability of the 19 suture without a coating?

20 MR. TAMBURO: Objection, asked and 21 answered numerous times, and mischaracterizes 21 that, you know, PE is added for lubricity and 22 prior testimony.

23 THE WITNESS: It's the basic and novel

24 characteristic, right, is improving -- yes.

25 that's, that's, it's, improving the

1 sorry to interrupt, what I was saying there was

220

2 that the, in my view, the claim controls first.

3 and that says consisting essentially of, and

4 that leads you right to the basic and novel

5 characteristics that we just talked about,

6 which is addressed in that second paragraph.

However, if we look to the 8 specification, which is the way Rich was

9 pointing in his correspondence with me, he kept

10 saying, look, you know, it says you can do

11 coating, you can do coating. And I say, even

12 if we look to the specification, you know,

13 first of all, I don't think that, that portion

14 that he pointed to is inconsistent.

15 But if we actually are going to take 16 the specification and put it in the claim as he

17 was proposing, in my view, then we definitely,

18 then there's, then we're doing the opposite in

19 terms of which component is being used for what 20 purpose because the specification is clear

22 polyester is the strength component in the

23 claimed suture, and in ours, the ultra high

24 molecular weight PE, which was being equated by

25 Ethicon as meeting the PE limitation, in part,

219

1 handleability is the basic and novel

2 characteristic, but by doing so, by effecting

3 the fiber-to-fiber frictional coefficient,

4 rather than by using the coating.

5 BY MS. MALINOSKI:

Q. In the -- and that was your position

7 back when you rendered your opinion on December

8 23rd, 2003, that was Exhibit 209, that was your understanding?

10 A. Yeah.

11 Ο. Okay.

12 A. Yes, I think it's reflected in that.

13 Q. And that's your understanding as of

14 February 20th, 2004?

A. Yes.

16 Q. And today?

17 A. And today.

18 Q. In the bottom paragraph, the third

19 paragraph of your, of your February 20th

20 letter, Exhibit 115, you're talking about

21 looking to the specification of the Hunter

22 patent, rather than the claims to define the

23 invention. What were you trying to do in that,

24 in that situation?

A. Okay. What I was saying there, I'm

1 strength, and the polyester, you know, is there 2 for handleability.

I mean, we had originally proposed a 4 suture that was, that I believe, that didn't

5 have polyester, that didn't handle well enough,

so the polyester was added for the

handleability characteristic, just the opposite

of what the patent speaks about.

Q. Are you aware that ultra high

10 molecular weight polyethylene is also

11 lubricious?

A. Yes. But my point is we were doing it

13 for opposite, I mean, for opposite purposes, if

14 we're going to look to the spec, if we are,

15 and, again, I think that the claim controls, 16 but if we are to look at the spec, we're doing

17 the opposite of what's in the spec. We're not 18 adding it.

19 The specification says you add it, you 20 add PE for lubricity. We don't add -- the

21 ultra high molecular weight component is not

22 there in the Arthrex suture for lubricity,

23 whether it has that or not, it's there for 24 strength.

Q. So then the intent of why, in your

242 1 But Arthrex, the patent is out there, Arthrex 2 now knows about the patent. Back in December 3 2003, two e-mail opinions were rendered that it 4 was said Arthrex was relying on to continue to 5 keep FiberWire on the market and continue to 6 launch new reiterations and new sizes and new variations of FiberWire. 8 So the question is, is Arthrex

9 releasing those new FiberWire products based 10 solely on the reliance on the December 4th, 11 2003 opinion and the December 23, 2003 opinion

12 or to defend against willful infringement, or 13 is it also relying on the defenses that are

14 being taken in this litigation? It's a simple 15 question. It's a yes or a no.

MR. TAMBURO: Well, I mean, relying on 16 17 the defenses in this litigation --18

MS. MALINOSKI: Relying on them to 19 defend against their allegations of willful 20 infringement, if you inject that into the case, 21 that you're relying on your good-faith defenses

22 in the litigation, sorry, you've waived, and 23 we're entitled to explore the basis for that.

24 If the answer is, no, Arthrex's 25 reliance is limited to those two particular 1 responses, and you're saying that you're

2 entitled to all of the work product that went

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3 behind these responses and supplemental 4 responses based on the discovery that the

5 attorneys learned from, from DePuy Mitek.

6 MS. MALINOSKI: If John Schmieding is 7 forming a reasonable basis that Arthrex has no 8 infringed the '446 patent and his reasonable

9 basis and good-faith belief that they do not

10 infringe or the patent is invalid is based on 11 more than those two opinions, yes, we are 12 entitled to explore it. You've waived.

13 THE WITNESS: In defense to the charge 14 of willful infringement.

MS. MALINOSKI: In defense to the 15 16 charge of willful infringement.

17 THE WITNESS: Well, I disagree because 18 I think that happens in every single, every

19 single litigation. So, I mean --

20 MR. TAMBURO: Good luck.

21 THE WITNESS: -- Arthrex, of course,

22 as the, as the defense -- as the discovery

23 continues and as more information is known, a

24 lot of defenses are buttressed, and this case 25 is no exception.

243

1 e-mails, that's what they relied on to continue

2 selling FiberWire, that's what they continue to 3 rely on as they come out with new iterations of

4 FiberWire, then the answer is, no, we're not

5 relying on the defenses in this case.

But if the answer is we are relying on 6 7 the defenses in this case to defend against the allegations of willful infringement, then we 9 are entitled to explore that.

10 MR. TAMBURO: Okay. Before any 11 discovery was taken, Arthrex relied on opinions 11 the client, with John Schmieding, it's fair 12 of counsel that it's -- these opinions were

13 rendered based on the information that counsel 13 to that. 14 had at the time.

15

MS. MALINOSKI: Correct.

16 17 them in good-faith, and we talked about those 18 this morning and all of the documents that we 19 produced in connection with those opinions. 20 MS. MALINOSKI: I understand that,

21 Sal.

22 MR. TAMBURO: Now, after the lawsui 23 was filed, Arthrex has no choice but to 24 generate a defense in response to that, and

25 now, it takes discovery and it supplements its

MS. MALINOSKI: Right. I don't, I

2 don't disagree with you, but I'll direct you to

3 the, I mean, the case law that addresses 4 these -- there's case law that addresses these

5 issues, and we're not going to resolve it here

6 today. So, you know, there's really no point.

But there are cases that work

8 product -- some cases, if it's communicated to

9 the client, and there's been ongoing

10 discussions here that have been going on with

12 game, and it's our position that we're entitled

14 MR. FALKE: What Lynn is saying, is 15 there is a difference between having defenses

MR. TAMBURO: And Arthrex relied on 16 and defending yourself in a litigation and

17 having good-faith reliance on opinions to

18 defend against a charge of willful

19 infringement.

20 MR. TAMBURO: What's the difference?

21 How do you separate the two?

22 THE WITNESS: Yeah, I mean, John

23 considers everything.

24 MR. FALKE: Like --

25 MR. TAMBURO: How do you separate the

EXHIBIT 23

Page 1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
C.A. NO. 04-12457 PBS

Danis Manner Tire

-----X

TRAVEL TRANSCRIPT

DePUY-MITEK, INC.,

A Massachusetts Corporation, Plaintiff,

VS.

ARTHREX, INC.,

A Delaware Corporation,
Defendants.

DEPOSITION OF DR. MATTHEW HERMES

Philadelphia, Pennsylvania

June 27, 2006

Reported by:

CONSTANCE S. KENT, CSR, RPR

JOB NO.: 350

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Page 248

Page 246 1 clearer source-based names, correct? 1 name for polyethylene. 2 A. Yes. 2 So this has turned out to be 3 Okay. Is it your understanding that 0. inaccurate at least over the period of 20 years. 3 4 this document is designed to try and clear up an 4 Isn't it true, though, that the 5 ambiguity that existed? rapid - that this document is teaching that there 5 6 No, it's my understanding that it's a 6 are being advances made in the structural 7 document describing generic source-based determination of polymers? 7 8 nomenclature. 8 A. Yes. What does it mean to you when it says 0. 9 O. And that - that the authors are it solves these problems and yields clearer 10 teaching that this will gradually shift the emphasis 10 11 source-based names? of polymer nomenclature away from the starting 11 12 Whatever problems there were, it's materials and toward the structure of the 12 13 attempting to clear them up. I'm sorry, I'm not 13 macromolecules? familiar with what the specific problems were. 14 14 A. Clearly that's their prediction, sir. 15 But you agree with me this document 15 0. That's what would be understood by 16 in 2001 is an attempt to clear up problems that one skilled in the art reading this around 1987 when 16 17 existed on names? 17 it was published, correct? 18 That's what it says sir, yes. A. 18 MR. BONELLA: Object to the form. 19 Q. Let's - let's go to Exhibit 18 if we 19 THE WITNESS: Correct. 20 could, please. 20 BY MR. SABER: 21 Indeed. Α. 21 Now, you're familiar with the use of 22 Q. Could you turn to page 193 of this ultra high molecular weight PE in the Arthrex 22 23 report? 23 FiberWire product, correct? 24 A. Yes. 24 A. Yes, I am. 25 Is it correct that this -- this Q. 25 And would you agree that the ultra Q.

Page 247 exhibit is saying that there are deficiencies of source-based nomenclature?

The -- the paragraph beginning the principal deficiency talks in general about a nomenclature problem that has been inherent in defining the names of polymers, yes.

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And if you look further down the paragraph, doesn't it conclude, the paragraph: The rapid advances now being made in the structural determination of polymers will gradually shift the emphasis of polymer nomenclature away from the starting materials and toward the structure of the macromolecules?

A. That's a -- that is the opinion of the authors.

Do you have any reason to disagree with the opinions of the authors?

I don't think I have enough knowledge to disagree with those authors.

Having said that, this was published in 1987, 20 years ago, and there's no -- there's no indication in the field of ethylene and polyethylene that anything of that kind is going on these days. Polyethylene is still polyethylene, and the -- the structural details do not appear in the source-based

Page 249 high molecular weight PE is added to the product to increase the strength of the suture?

MR. BONELLA: Objection. Outside of scope of his expert report.

THE WITNESS: You know, I'm familiar -- I'm familiar with the product, sir, and with some of its test properties that have been shown to me, but the -- I'm familiar with Grafton's patent, but the motives -- the specific motives at the time and place I can't comment on. BY MR. SABER:

You are familiar that ultra high 0. molecular weight PE is a high strength product?

That fibers of ultra high molecular weight have high tensile strength, yes.

And you agree that -- that -- you've heard the nomenclature high strength sutures in the marketplace, the sutures today?

19 I'm not in the market today, 20 Mr. Saber. I don't know exactly what you're -- what you're asking. My expertise is in the period '88 --21 '86 to '92, and whatever has happened in connection 22 with this case over the last three months, so I'm 23 24 not fully aware of today's marketplace, if that's 25 what you're asking me.

Case 1:04-cv-12457-PBS Document 68-7 Filed 09/15/2006 Page 1 of 14

EXHIBIT 24

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation))
Plaintiff,)
v.) Civil No. 04-12457 PBS
Arthrex, Inc. a Delaware Corporation and)))
Pearsalls Ltd., a Private Limited Company of the United Kingdom,)))
Defendants.	,)

Expert Report of Dr. Matthew Hermes

I. Background Information

A. Professional Experience

1. From 1983-95, I was employed with U. S. Surgical Corp. In 1983, I started as Senior Research Scientist. My duties from 1983-1986 included developing products based on bio-absorbable materials for use as medical devices. From 1986-1992, I initiated and led the first suture development program at U.S. Surgical. That program led to the commercialization of the Syneture™ suture product line. My responsibilities included all phases of surgical suture development from concept to commercialization. My suture group included seventeen team members directly involved in the design and development of commercial surgical suture products, including suture design and manufacture, fiber extrusion and processing, fiber design, yarn design, braiding specifications, selection of materials, braid design, prototype braiding, braid post

- D. If The Claims Of The 446 Patent Are Construed To Mean That "PE" Includes UHMW PE, Then The 446 Patent Is Non-obvious Over Burgess And i) Cohan; ii) The DSM Brochure; And/Or iii) The Harpell Patents
- 86. My below opinions assume that the claims of the 446 Patent are construed to mean that "PE" includes UHMW PE.
 - It Is My Opinion That Claims 1, 2, 8, 9 and 12 of the 446
 Patent Are Not Invalid For Obviousness Over Burgess In View Of Cohan
- 87. Dr. Mukherjee states that claims 1, 2, 8, and 12 of the 446 Patent are invalid as obviousness over Burgess in view of Cohan. I disagree. Below I discuss the teachings of Burgess and Cohan to one of ordinary skill in the art between 1988 and 1992.
 - a) The Scope And Content Of Burgess
- 88. Burgess discloses fishing lines (Ex. 7 at 1), not suture or medical devices. Burgess discusses certain desirable properties of a fishing line, but does not mention certain suture properties, such as knot security or knot strength (Ex. 7 at 1). Burgess does state that fishing lines "require... non-stretchability" (Ex. 7 at 1). Burgess states that "non-stretchability" is a fishing line requirement, not a preference (Ex. 7 at 1).
- 89. Burgess further discloses a fishing line that should have a "braided construction" (Ex. 7 at 1). Burgess discloses that some filaments are of "high tensile polythene thread" and other filaments are "polyester and/or nylon" (Ex. 7 at 1). But Burgess does not disclose what kind of "braided construction" he envisioned, how to construct the braid which he references, nor how to use the materials in the "braided construction" he references. For example, Burgess does not disclose whether the polythene thread should be in the core, whether it should be in the sheath alone, or in the sheath with another material. Nor does Burgess disclose whether the polyester and/or nylon alone

should be in the core, whether it should be in the sheath alone, or in the sheath with another material. At no point does Burgess state that the polythene can be in a sheath with another material such as nylon or polyester.

- 90. In fact, the Burgess disclosure is at most two double-spaced pages. Burgess has no drawings; Burgess provides no working detail or explanation whatever of the braided fishing-line construction which he references. Nor does he provide any description of how to make the "braided construction" to which he refers or the type of equipment that should be used to fabricate the "braided construction" for a fishing line.
- 91. Burgess discloses the use of high molecular weight polythene in a fishing line. However, one of ordinary skill in the art would know that high molecular weight polythene is a lubricious material with poor knot security and knot tie down characteristics. Burgess does not disclose how to overcome these characteristics of high molecular weight polythene. Notably, Mr. Grafton, former Arthrex employee and developer of FiberWire, also stated that UHMW PE was typically used for fishing line and did not have acceptable knot tie down characteristics for use in sutures (Ex. 14 at 1:14-20). Mr. Grafton also stated that the poor knot slippage of UHMW PE was due to its lubricity (Ex. 12 at 53). Thus, Burgess discloses high molecular weight polythene, which is known to be a lubricous material, but does not describe how to construct an acceptable suture with UHMW PE.
- 92. I disagree with Dr. Mukherjee about the scope and content of Burgess. Dr. Mukherjee states that "the Burgess application discloses every limitation of claim 1 of the '446 patent . . . except that Burgess is not a sterilized suture" (Mukherjee at 17). But Dr. Mukherjee does not provide any analysis as to where the claimed limitations are

found in Burgess. Nor does he explain why Burgess necessarily teaches the braid claimed in the 446 patent, as opposed to some other braid construction. Thus, I disagree with his reading of Burgess.

93. Dr. Mukherjee uses the prosecution history of the 446 patent to support his reading of Burgess. I disagree that the prosecution history supports his analysis. Dr. Mukherjee cites to the Examiner's statement that "Burgess discloses a fishing line of braided construction comprising filaments of polyethylene and filaments of polyester or nylon," and suggests that the Examiner stated that the "braided construction" of Burgess was the same as the claimed "heterogeneous braid" of yarns in "direct intertwining contact." But the Examiner never said this. Notably, the Examiner never stated that Burgess discloses the claimed "heterogeneous braid' of yarns in "direct intertwining contact." Rather, the Examiner only stated that Burgess disclosed a "braided construction," not any specific braided construction, and then concluded it would have been obvious in light of Burgess to form the claimed invention of then pending claims 21-24. Thus, contrary to Dr. Mukherjee's suggestion, the Examiner never stated that Burgess discloses a heterogeneous braid of UHMW PE and Polyester or nylon in "direct intertwining contact" as claimed in the 446 patent.

b) The Scope And Content Of Cohan

94. Cohan discusses the use of an ultra strong polyethylene fiber in an ophthalmic suture. According to Cohan, the "polyethylene fibers are monofilaments with a ribbon shape." It also describes three monofilaments made from nylon, polypropylene, and polyester. The Cohan article discusses testing each of these monofilaments. The testing results are summarized in Figs. 2-4 and Tables 1-3. Figure 2 shows that a continuous filament of polyethylene has a greater tensile strength at break than the

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c) The Differences Between Burgess And Cohan And Claim 1 of the 446 Patent Are Significant

- There are many differences between claim 1 of the 446 patent and the combination of Burgess and Cohan. These differences indicate the non-obviousness of claim 1 of the 446 patent.
- 104. Claim 1 of the 446 Patent claims a suture. Burgess only describes a fishing line.
- Claim 1 of the 446 Patent claims a heterogeneous braid where at least one set of 105. yarns from the first group is in direct intertwining contact with at least one yarn from the second group. Burgess does not teach this. In fact, Burgess is entirely silent on the construction of the fishing line or its method of assembly. Thus, Burgess does not teach the braid recited in claim 1 of the 446 Patent.
- 106. Also, because Burgess does not describe the braided construction he references and does not describe how to make it, Burgess does not enable one skilled in the art between 1988 and 1992 to make and use a suture of claim 1 of the 446 Patent. I do not understand how Dr. Mukherjee considers Burgess to be detailed enough to teach one of ordinary skill in the art in 1992 how to make and use the claimed heterogeneous braid of the 446 Patent, and at the same time opine that the 446 Patent, which is much more detailed than Burgess, does not enable one of skill in the art to make and use the invention claimed in the 446 Patent. Burgess simply does not describe any type of braiding construction, braiding equipment or any braid manufacturing or processing. Likewise, Cohan does not teach the invention of claim 1 of the 446 Patent. Nor does Cohan fill in the gaps left by Burgess. Cohan does not teach a heterogeneous braided suture. Further, the Cohan article does not teach the materials recited in claim

discussed below there is no motivation based on their teachings or the level of skill in the art for several reasons.

- 111. First, because of the significant differences between Burgess and Cohan and claim 1 of the 446 patent, one of ordinary skill in the art would not have been motivated between 1988 and 1992 to modify Burgess to form the claimed invention. For example, neither describes the claimed heterogeneous suture braid of claim 1 of the 446 Patent, and there is no motivation or suggestion to combine the references to form the claimed braided suture.
- 112. Second, because Burgess does not describe knot security or knot strength, one of ordinary skill in the art between 1988 and 1992 would not have been motivated to use the teachings of Burgess to make a suture. Knot security and knot strength are two important suture properties. Therefore, Burgess' discussion of different requirements for fishing line and failure to mention knot strength or knot security would cause one of ordinary skill in the art not to be motivated to use Burgess' teachings in designing a suture.
- 113. Third, Cohan recognizes that monofilament PE has lower knot holding strength and posits overcoming this problem by tying more complex knots. Burgess says nothing about knot holding strength or how to solve the issues raised by Cohan. Thus, one of ordinary skill in the art would not have been motivated to combine Burgess and Cohan to form the claimed invention because he would have focused on trying to resolve the knot holding strength issues raised by Cohan by tying different knots.
- 114. Fourth, Cohan teaches that monofilament UHMW PE had disadvantages including lower knot holding strength, requiring more complex knots, spontaneous

untying, and unraveling, leading to irritation. Given these problems with the UHMW PE monofilament in Cohan, one of ordinary skill in the art having read Cohan between 1988 and 1992 would not have been motivated to further pursue using UHMW PE without first solving these issues.

- Fifth, even assuming that one of ordinary skill in the art would have been motivated to pursue the teachings of Cohan, Cohan teaches away from braiding. Cohan teaches trying to design a suture that was stronger than multifilament silk suture, but still had silk's handling properties by tying more complex knots. One of ordinary skill in the art between 1988 and 1992, who had read Cohan, would have focused on monofilaments, tying different types of knots, and eliminating unraveling, not braiding. 116. I have read Dr. Mukherjee's report and Dr. Mukherjee does not specify any motivation for combining the Burgess reference with the Cohan article. He also ignores the differences between the monofilament described in Cohan and the claimed invention of the 446 Patent and the problems noted by Cohan with UHMW PE. Thus, I disagree with his opinion.
- 117. I note that Dr. Mukherjee states that "it would have been obvious to a person of ordinary skill in the art, in February 1992, to use a heterogeneous braid, such as that disclosed in the Burgess application, for a suture" (Mukherjee at 18). I disagree for the reasons set forth above, but note that the general problem with this statement is that Burgess does not disclose any specific braid construction. Thus, one of ordinary skill in the art reading Burgess in 1992 would not have been able to just simply use a braid disclosed by Burgess as a suture, as Dr. Mukherjee suggests.

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Burgess, Burgess does not disclose any particular braid, and he would be led down a path of designing a suture to achieve the fishing line properties disclosed in Burgess, not a suture that maximizes suture properties. Burgess says nothing about how to make a braid to achieve knot security or knot strength.

195. At trial, I may use demonstrative exhibits that I have not yet created to further explain my opinions.

Dated: March 24, 2006

MattheweHermes Ph.D.

HERMES EXPERT REPORT EXHIBIT 7

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- (51) INT CL A01K 91/00, Do4C 1/12
- (52) UK CL (Edition J) A1A A19 D1K K14 U18 \$1022
- (56) Documents cited None
- (S8) Field of search
 UK CL (Edition J) A1A, D1K
 INT CL* A01K, D04C

- (54) Improvements relating to fishing lines
- (57) A fishing line of braided construction has some filaments of high tensile polythene. The other filaments are of polyesterer and/or nylon, and the braid may be coated with a sheath of polyurethane.

"Improvements relating to Fishing Lines"

This invention relates to fishing lines.

Fishing lines require many qualities, such as high tensile strength, while having a small diameter, non-stretchability, resistance to abrasion, smooth running and suppleness. It is the aim of this invention to provide a line embodying most of these not usually very compatible properties.

According to the present invention there is provided a fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

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The high tensile polythene gives the line minimal stretchability and will preferably be a high molecular weight polythene, melted in a solvent and drawn at high speed into extremely fine strands. This produces almost perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade_Mark_DYNEEMA.

With polyester, multifilaments will generally be used, and the more there are of them in proportion to the polythens the stiffer the line will be. With nylon, monofilaments will preferably be used and the principal effect will be a low coefficient of friction.

-1-

-2-

It would be possible for certain applications to combine both polyester and nylon with the polythene thread.

The braid may be coated with a thin, supple and smooth sheath of polyurethane and this may be carried out by a simple immersion process in liquid polyurethane. It will alter the characteristics (such as buoyancy and strength) in a predictable manner, but its main purpose is to prevent saturation of the interstices of the braid. In very cold conditions, such as fishing through holes in ice, water having worked its way into the braid will freeze and impart a brittleness that can lead to breakage.

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CLAIMS

- 1. A fishing line of braided commstruction, some braid filaments being of high temssile polythene thread and other filaments being of polyester and/or nylon.
- 5 2. A line as claimed in Claim 1,, wherein the other filaments include polyester moulti-filaments.
 - 3. A line as claimed in Claim 1 or 2, wherein the other filaments include hylon monorfilaments.
- 4... A.line as claimed in Claim 1., 2 or 3, wherein the braid is coated by a sheath of polygurethane.
 - 5. A line as claimed in any preeceding Claim, wherein the polythene is that sold Indeer the Trade Mark DYNEEMA.